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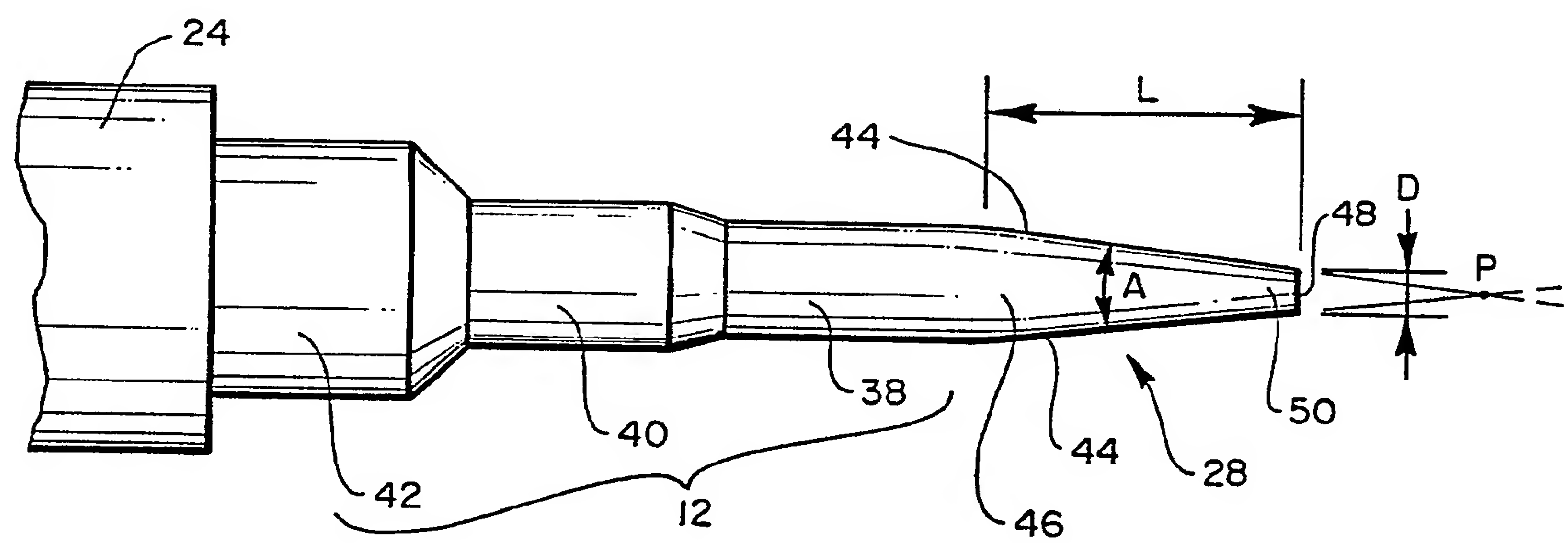

(57) Abstract

End structures for a medical laser fiber (38) integrally formed from a molten portion of the fiber (38) have sides free from polishing abrasions. The end structure may assume a frustoconical shape (28, 60) with sides (44) tapering smoothly from the fiber (38) to a flat surface (48) normal the axis of the fiber (38). Alternatively, a spherical (184) portion having a diameter (E_1) greater than the fiber (38) is disposed concentrically with the fiber (38). The end structure may include a bend portion (132, 152, 162, 202) diverting therefrom at a bend angle (B, B_1, B_2, B_3), being radially coextensive with the end of the fiber (38), and ending in a tip that assumes a spherical shape (208) or a frustoconical shape (134, 154, 164) that tapers to a flat surface (142) normal the plane of the bend portion (132) and parallel the fiber (38). An alternate tip embodiment has sides (104) that flare smoothly from the fiber (38) to a terminus (100) having a diameter (D_3) greater than the diameter of the fiber (38).

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INTEGRAL END STRUCTURE FOR MEDICAL LASER WAVEGUIDE

BACKGROUND

1. Field of the Invention

This invention relates to optical waveguides for medical use to transmit laser energy from a medical laser to tissue to be treated according to a medical procedure. More specifically, the present invention relates to a tip for focusing laser energy from the output end of an optical fiber core used in medical procedures, including those undertaken on the walls of passageways in the body.

2. Background Art

Laser energy has been used for some time in a variety of medical and surgical procedures to coagulate, vaporize, excise and anastomose selected body tissues. Lasers are now routinely used, not only to remove tissues in surgical procedures, but to induce hemostasis, to close blood vessels, ducts and other body passageways, and to destroy obstructions in body passageways. Such obstructions include, for example, fatty deposits, plaque, calcification, and embolic clots that develop in blood vessels.

The nature of each application determines the appropriate manner in which to configure and operate the laser delivery system. This includes the type of laser to

employ, and the laser intensity and time exposure that should be used.

For example, conventional argon lasers emit light in the blue and green wavelengths of 454.5 to 514.5 nanometers (nm). Energy at such wavelengths is readily absorbed by the hemoglobin found in red blood cells. Thus, argon lasers have been used to coagulate small vascular abnormalities, such as port wine strains, telangiectasias, spider veins, and diabetic retinopathy.

On the other hand, dye pumped argon lasers, flash pumped dye lasers, double neodymium yttrium aluminum garnet (Nd:YAG) lasers, and copper vapor lasers emit yellow light having wavelengths in the 530 to 590 nm range. Light in these wavelengths is even more readily absorbed by hemoglobin than is the blue-green light of the conventional argon laser. Accordingly, the conventional argon laser has recently been displaced in coagulating small vascular abnormalities by lasers that emit yellow light.

The light emitted by a primary neodymium yttrium aluminum garnet (Nd:YAG) laser is, on the other hand, only minimally absorbed by hemoglobin. Light from this laser tends to penetrate and scatter into tissue and shows little or no selectivity for coagulation of the blood vessels therein. Due to this property of the light of the primary Nd:YAG laser, it is used instead to coagulate large volumes

of tissue. The primary Nd:YAG laser is now used to facilitate in vivo removal of tissue with minimal bleeding.

Typically, the laser energy for use in such medical procedures is transmitted from the laser dictated by the application involved through an optical waveguide to the tissue to be treated. The waveguides most often take the form of a fiber core of optically transmissive material having an input end for receiving the laser energy and an output end remote therefrom for delivering the laser energy to the tissue. Hand-held probes are optically coupled at the output end of the optical waveguide. Initially, these probes were not designed to make contact with the tissue being treated.

A disadvantage of this feature of laser energy transmission systems resided in an inability to efficiently deliver all of the energy in the waveguide to the precise tissue to be treated. The separation between the tissue and the output end of the optical waveguide encouraged the scattering of laser energy, as that energy was required to pass first through the optical interface between the probe and air and then through a second optical interface between the air and the tissue. In addition, this same separation resulted in a defused pattern of laser energy in or on that tissue, preventing the efficient and selective delivery of the laser energy to the precise tissue needing to be

treated. This caused unwanted destruction in surrounding tissues.

As a result, laser probes were developed which make direct contact with the tissue to be treated or, at a minimum with the layer or layers of tissue lying immediately thereover. Various focusing structures were utilized at the output end of the optical waveguides employed in these contact laser probes. The focusing structures directed the laser energy emerging from the waveguide in a pattern conducive to the medical procedure being undertaken.

In United States Patent No. 4,273,127 the focusing structure takes the form of a scalpel-shaped optically transmissive body mounted at the output end of an optical fiber core so that laser energy delivered from the fiber will emerge from the light guide at the cutting edge thereof in a cone-shaped pattern. A surgeon is able to effect tissue incision both by applying pressure to the scalpel-shaped body, and by utilizing laser energy.

In the laser probe disclosed in United States Patent No. 4,592,353 a lens and cover separate from an optical fiber core are interposed at the output end of the fiber core in order to produce a structure specifically designed for tissue coagulation. The contact probe disclosed in United States Patent No. 4,693,244 comprises an optical fiber core with a separate focusing structure in the form

of an artificial sapphire with a tapered extremity. The larger end of the sapphire is positioned opposite the output end of the optical fiber core with an air gap therebetween, permitting the tapered end of the sapphire to contact tissue for surgical treatments, such as incision, coagulation, and hemostasis. United States Patent No. 4,736,743 discloses a similar probe tip, distinct from the optical fiber core of the delivery system, and made of a natural or artificial ceramic material. In each reference, the focusing structure at the output end of the optical fiber core is a structure distinct from the fiber core itself. This requires optical and physical coupling between the two components of the system.

Contact probes having tips that require optical and physical coupling to the output end of an optical fiber core have numerous drawbacks. Due to the near physical difficulty of exactly matching the flat faces of the opposing faces of the sapphire and the fiber core, for all practical intents an air gap results between the two components. First, a substantial loss of laser energy occurs as the laser energy from the optical fiber core crosses into the air gap at the output end of the fiber core and thereafter crosses from the air gap into the input end of the focusing tip. This dissipation of laser energy, expectable at an interface between materials of differing refraction indexes, dissipates energy that could otherwise

be delivered to the tissue to be treated. Moreover, it is a loss which manifests itself in a form of the generation of heat.

Heat produced at the interface between the output end of an optical fiber core and a distinct focusing tip coupled thereto, has a number of adverse consequences. First, the resultant thermal stress accelerates aging of the probe tip and the optical fiber core. This contributes to rapid failure rates in the components of the probe, increasing the cost of its use and the downtime for its repair.

In endoscopic applications, the waste heat generated at the interface between the output end of the optic fiber core and the separately formed focusing tip used therewith must be removed from the body of the patient. Failure to promptly and completely do so can cause damage in tissues surrounding the site, leading to complications and extended healing times. The mechanisms for effecting this cooling process require the introduction and removal of fluid or gas coolants into the body of the patient. These are not only costly systems, but being relatively complex, they are susceptible to regular breakdowns. Even a momentary malfunction risks unnecessary tissue damage, where the lasers being cooled thereby is not also promptly de-energized. Cooling systems also introduce into the surgical site alien materials, some of which have in recent

years been suspected of causing fatalities due to embolisms or other bodily reactions to the chemicals and heat involved.

Focusing structures which are distinct from the optical fiber core to which they are coupled are generally manufactured from crystalline materials, such as sapphire, diamond, and quartz. Unfortunately, the crystalline structure of such materials places restrictions on the shape of focusing tips that can be manufactured therefrom. The sides of tips made of such crystalline materials cannot be made to be smoothly tapering or smoothly flaring without polishing. Doing so, however, creates fine polishing abrasions on the surface of the tip corresponding to the size of the polishing abrasive employed in the process. The presence of polishing abrasions on the sides of a crystalline tip for an optical waveguide causes part of the laser energy reaching the tip to be diffused through those sides. This impacts adversely the transmission efficiency of the resulting probe. By scattering laser energy from the sides of the focusing structure, rather than from the tip thereof, undesirable coagulation is also caused in tissue adjacent to but not precisely at the end of the tip.

The cost of growing, polishing, and installing crystalline structures of the size required for the tip of a laser fiber core is relatively high. When the focusing structure on a laser probe is distinct from the optical

fiber core thereof, complicated means of mechanically coupling these two components must be utilized. Such means of coupling include press fittings, jewelry-style prongs, and adhesives. These impact the cost of the resultant structure, and each is afflicted with increased risk that tip components loosen. This necessitates repair, or even a search in the surgical site for a completely detached tip component. These factors not only make the cost of producing composite waveguides so high as to mandate their sterilization and reuse, eliminating the possibility of disposability.

Even where an attempt to avoid some of these problems is made by fabricating a focusing structure that is integral with the end of an optical fiber core, polishing is used to shape that focusing structure. Accordingly polishing abrasions are found on the sides of the tip, and this degrades its internal reflectiveness.

It should also be noted that polishing abrasions constitute surface flaws in such tips. As such the polishing abrasions can start fractures that cause tip failures, a correlation is possible between the presence of such surface abrasions and a lack of structural solidity in the probe tip on which they exist.

Particularly difficult surgical conditions exist in relation to endoscopic procedures to be effected on the walls of tubular passageways in the body, such as those of

the circulatory, digestive, urological and respiratory systems. Typically the output end of the laser probe utilized is advanced within the bodily passageway involved to the site of the required surgery. Nevertheless, the tip structure of known probes directs laser energy therefrom in a direction that is parallel to the longitudinal axis of the probe, which is also parallel to the bodily passageway in which the probe is located.

It is most difficult, therefore, to direct laser energy toward a surgical site that is on the immediate wall of the passageway. Laser energy is instead directed along the axis of that passageway, posing the risk of inadvertently damaging the walls of the passageway at any point ahead of the laser probe tip where the passageway curves. To orient the tip of such laser probes laterally toward the immediate wall of the passageway, it has been necessary in the past to resort to auxiliary structures which grasp the laser probe at the output end thereof and bend it toward the desired surgical site. Such auxiliary equipment by adding to the complexity and the size of the probe involved increases cost, decreases reliability, and limits the smallness of the bodily passageway in which such surgical procedures can be effectively and safely undertaken.

In some prior devices, the desired end has been achieved by a composite structure involving a brass cap

with a lateral window therethrough which is placed over the end of a bare optical fiber. Laser energy transmitted to the end of the fiber is reflected internally until it passes through the window to be focused on the tissue of a tubular body passageway adjacent thereto. Naturally in this process of internal reflection substantial heat is generated in the metallic cap, posing a hazard to adjacent tissue which is not targeted for treatment by laser surgery.

As the capacity develops to deliver laser energy to a surgical site while maintaining high transmission efficiency, equipment refinements to meet specific of the diverse needs of the laser surgeon can be expected. Some surgical procedures will require the precision focusing of laser energy in order, for example, to effect a cutting function. By cutting, sections of tissue can be detached and thereafter removed from the surgical site. On the other hand, it may be desired that tissue removal can be effected by direct vaporization. To do so will require laser energy to be transmitted in a broad, intense beam onto a large area of tissue. In certain endoscopic applications, for example, it may be desirable to vaporize tumorous tissue, removing the vapor from the body cavity, rather than detaching the tumor and then cutting it into small pieces that can be manipulated out of the surgical site through a small opening thereinto. The desirability

of either of these options can arise when the surgical site is located on the wall of a passageway immediately to the side of the laser probe, rather than axially alignable with the laser probe. Additionally, it has been discovered that certain patterns of laser energy transmission are more effective than others in producing hemostasis during laser surgery. Accordingly, the need exists to develop surgical laser contact tips capable of transmitting laser energy in a variety of patterns and intensity.

An additional problem encountered in the area of laser waveguides, such as those used in medical procedures, arises because the splicing together of two or more optical fiber cores requires for a satisfactory transmission interface therebetween that the output end of one of the fiber cores be smaller in diameter than the input end of that to which it is to be optically coupled. Thus, each optical fiber core in a sequence of fibers spliced together to effect a lengthy transmission must be larger in diameter than the preceding fiber core. Where an optical laser fiber core becomes damaged, and the damage is to be remedied by coupling a section in substitute therefor, the input end of that new section must have a diameter larger than that of the fiber core being repaired. On the other hand, the output end of that new section must be reduced in diameter relative to the fiber core being repaired. This is often accomplished by tapering that output end of the

new section using polishing. With laser applications, this produces undesirable diffusion through the sides of the taper, contributing to a buildup of heat and a loss of transmission efficiency.

SUMMARY OF THE INVENTION

One object of the present invention is to produce an optical waveguide for use in medical procedures which reduces to a minimum the loss of laser energy at the tip thereof.

Another object of the invention is an optical waveguide as described above which eliminates heat generation conventionally found at any transmission interface between an optical fiber core and any focusing structure at the tip thereof.

It is accordingly a related object of the present invention to eliminate heat shielding for medical personnel utilizing the optical waveguides described above and to produce a contact laser probe suitable for endoscopic use which does not require in complementary use therewith complicated and dangerous cooling systems that introduce additional alien materials into the body of the patient.

It is a further object of the present invention to produce a contact laser probe as described above which is effective in endoscopic procedures on the inner walls of

tubular passageways of the body, such as those of the circulatory, digestive, urological and respiratory systems.

Still another object of the present invention is to produce a tip for focusing laser energy from the output end of an optical fiber which is free on the sides thereof from polishing abrasions, but which nevertheless focuses optical energy from the optical fiber in a pattern conducive to the medical procedure to be undertaken.

In addition, it is an object of the present invention to produce a contact laser probe in which the index of refraction of the tip thereof is closely matched to the index of refraction of the fiber core with which it is used and with the tissue to be contacted.

Furthermore, it is an object of the present invention to eliminate loose or lost focusing structures in contact laser probes.

It is yet another object of the present invention to reduce the cost of manufacture of contact laser probes to such an extent as to render such products inexpensive enough to be disposable after a single use.

Yet another object of the present invention is to simplify endoscopic medical laser procedures.

Yet another object of the present invention is to eliminate undesirable tissue coagulation at the sides of the focussing tip in a contact laser probe.

Yet an additional object of the present invention is to provide a laser surgeon with laser probes capable of transmitting laser energy in a variety of patterns each optimally suited toward various specific ends, such as cutting tissue, vaporizing tissue, or effecting hemostasis. It is intended to achieve these ends even where the site of the surgical procedure involved is laterally adjacent to the laser probe on the inner wall of a passageway in the body.

Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims.

To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, a contact laser probe is provided for coupling to a laser to transmit laser energy to a living tissue or other material for treatment according to a predetermined procedure. The probe comprises a fiber core formed of an optically transmissive material, and having an input end for receiving laser energy from the laser and an output end remote therefrom for delivering the laser energy to tissue to be treated according to a specified medical procedure.

The optically transmissive material preferably has an index of refraction similar to that of the tissue to be treated.

The probe further comprises an end structure of the same optically transmissive solid material integrally formed on the output end of the fiber core, generally from a molten portion thereof. The side surfaces of the end structure are free of polishing abrasions, thereby minimizing the diffusion of laser energy therethrough. This enables controlled focusing of the laser energy from the fiber core onto the tissue.

In one preferred embodiment of the invention, the end structure comprises an axially aligned tip having sides that taper smoothly from a first end adjacent to the fiber core to a terminus at the second end, which is remote from the fiber core. That terminus comprises a flat surface disposed normal to the longitudinal axis of the fiber core. The tip in this embodiment may be generally described as being frustoconical in shape.

In a preferred embodiment of the axially-aligned, tapered form and the invention, using a fiber core of about 600 microns in diameter the tip has a length in the range of about 1.5 millimeters to about 7.0 millimeters and a diameter at the terminus thereof in the range of about 75 microns to about 300 microns. Alternatively, the apex angle formed by projecting the sides of the tip to an

intersection beyond the terminus is preferably in the range of about 4° to about 45°.

Additionally, the disclosed invention includes a method for making an axially-aligned, tapered tip for an optical waveguide for use with a medical laser. In the method, a first portion of a length of fiber core of optically transmissive material located intermediate second and third portions of the fiber is heated to render the first portion molten. Thereafter, the third portion of the fiber core is drawn away from the heated first portion parallel to the longitudinal axis of the fiber, thereby to produce from the heated first portion a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from the second portion. The shape is cooled and scored at a point located a predetermined distance along the shape from the second portion of the fiber core. Finally, the shape is broken at the scoring point to form from the shape integrally with the second portion of the fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through the fiber core to the second portion thereof. The tip is polished to produce at the end remote from the second section of the fiber core a terminus comprising a flat surface disposed normal to the longitudinal axis of the fiber core.

In another, off-axis tapered embodiment of the invention, the end structure comprises a generally cylindrical bend portion having a proximal end radially coextensive with the output end of the fiber core and a distal end opposite therefrom. The longitudinal axis of the distal end of bend portion diverts from the longitudinal axis of the output end of the fiber core at a predetermined bend angle. A tip is formed on the distal end of the bend portion having sides that taper from a first end adjacent to the bend portion of the end structure to a terminus at the second end, which is remote from the fiber core. The terminus comprises a flat surface which may be disposed normal to the longitudinal axis of the tip. Preferably, however, the terminus is disposed normal to the plane of the bend portion and parallel to the longitudinal axis of the fiber core at the output end thereof. The tip in this embodiment may be generally described as being frustoconical in shape. The optically transmissive material preferably has an index of refraction similar to that of the tissue to be treated.

By bringing the terminus of the tip of the end structure into contact with the wall of a bodily vessel, laser energy may be accurately and directly transmitted to tissue in the wall of a bodily passageway despite the output end of the probe being disposed generally parallel thereto. If the terminus of the tip is pressed against or

into the tissue of the passageway, it has been found that laser energy is transmitted from the tip into the contacting tissue primarily along the side surface of the tip that is located on the same side of the end structure as is the inner side of the curved bend portion. Naturally, in addition to being employable in a contact mode, the tip can be backed off of the material receiving treatment into a so-called diffused mode in which the laser beam has decreasing intensity and an enhanced hemostatic effect.

In a preferred embodiment of the tapered, off-axis form of the invention, the predetermined bend angle at which the longitudinal axis of the bend portion diverts from the longitudinal axis of the output end of the fiber core is in the range of about 15° to about 60° or more preferably in the range from about 25° to about 45°. Using a fiber core of about 600 microns in diameter the tip has a length in the range of about 1.5 millimeters to about 7.0 millimeters and a diameter at the terminus thereof in the range of about 75 microns to about 300 microns. Alternatively, the apex angle formed by projecting the sides of the tip to an intersection beyond the terminus is preferably in the range of about 4° to about 45°.

Additionally, the disclosed invention includes a method for making a tapered, off-axis end structure for an optical waveguide for use with a medical laser. In the

method, a first portion of a length of fiber core of optically transmissive material located intermediate second and third portions of the fiber is heated to render the first portion molten. Thereafter, the first portion of the fiber core is bent so that the longitudinal axis of the third portion is at a predetermined angle to the longitudinal axis of the second portion, creating the bend section of the invention. The second portion is then cooled, and a tip for narrowly focusing laser energy from the medical laser is formed from the first portion of the fiber core.

The tip is formed by processing the third portion of the fiber core as described below. A first section of that third portion located intermediate second and third sections of the third portion is heated to render the first section molten. The second section of the third portion is located adjacent to the first portion of the fiber core from which the bend section thereof was generated. Heating steps may be accomplished through the use of an oxygen acetylene flame, an electric arc, high frequency radio signals, or the application of a laser.

Thereafter, the third section of the third portion of the fiber core is drawn away from the heated first section parallel to the longitudinal axis of the first portion of the fiber core at the end thereof remote from the second portion thereof. This produces from the heated first

section a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from the second section. The shape is cooled and scored at a point located a predetermined distance along the shape from the second portion of the fiber core.

Finally, the shape is broken at the scoring point to form from the shape integrally with the second section of the third portion of the fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through the fiber core to the second portion thereof. The tip is polished to produce at the end remote from the second section of the fiber core a terminus comprising a flat surface disposed normal to the plane defined by the second and third sections of the first portion or the first section of the third portion of the fiber core, but parallel to the longitudinal axis of the fiber core.

In one embodiment of the invention, the end structure is an orbicular, axially aligned structure that comprises a lens portion disposed at the output end of the fiber core concentric with its longitudinal axis and a transition portion smoothly connecting the surface of the lens portion to the sides of the fiber core. Typically, the lens portion is orbicular, or spherical, having a diameter that is greater than the diameter of the fiber core.

The end structure functions in two distinct operative modalities. In the carrier mode of transmission, a portion

of the laser energy corresponding to low order rays of laser energy delivered from the output end of the fiber core are focused through a fast focal point aligned with the longitudinal axis of the fiber core at the output end thereof. As used herein and in the appended claims, the portion of the laser energy corresponding to low order rays that is focused through the fast focal point will be referred to as a "second portion" of that laser energy. This modality of transmission is operative under all conditions, whether or not the end structure is in contact with tissue to be treated according to a medical procedure.

Nevertheless, when the end structure is brought into contact with such tissue, an avalanche mode of transmission results in which multi-directional laser energy is transmitted through such portions of the surface of the end structure as make contact with the tissue. The multi-directional laser energy transmitted in this manner corresponds to high order rays of laser energy delivered from the output end of the fiber core into the lens portion of the end structure. There such high order rays of laser energy become internally star-reflected about the inside of the lens portion forming a region of multi-directional laser energy. This multi-directional laser energy is then available for transmission in the avalanche mode through any portion of the surface of the end structure which contacts the tissue to be treated. As used herein and in

the appended claims, the portion of the laser energy corresponding to high order rays that are internally star-reflected in the lens portion of the structure will be referred to as a "first portion" of that laser energy.

Due to the enlarged size of the lens portion of the end structure relative to the fiber core, the laser energy transmitted in the avalanche mode of transmission can thus be applied to a large area of the tissue simultaneously, a transmission pattern which is effective in rapid vaporization of large volumes of tissue, while producing very desirable hemostasis characteristics. The orbicular structure is thus an ideal contact laser probe tip for vaporizing larger areas of tissue that are contacted by the laser probe tip itself.

In a preferred embodiment of the invention, the diameter of the lens portion is in the range of about 0.6 millimeters to about 3.0 millimeters, or more preferably in the range of from about 0.8 millimeters to about 2.5 millimeters. Using a fiber core of about 1.0 millimeters in diameter, the lens portion has a diameter of about 1.2 millimeters.

Additionally, the disclosed invention includes a method for making such an axially aligned orbicular end structure from optical waveguide for use with a medical laser. In the method, the end of an optical fiber is oriented in a generally vertical direction and rotated

about the longitudinal axis thereof. A first portion of the length of the fiber adjacent to the end thereof is heated, thereby rendering it molten. The heated portion of the fiber core is permitted to assume a bulbous shape having smoothly flaring sides and a diameter that is greater than the diameter of the fiber. The bulbous shape is then cooled. In the heating step the end of the optical fiber core is oriented downwardly at an inclination angle to the vertical in the range of from about 10% to about 15%.

In another orbicular embodiment preferred invention that has an off-axis configuration, the end structure comprises a generally cylindrical bend portion having a proximal end radially coextensive with the output end of the fiber core and a distal end opposite therefrom. The longitudinal axis of the distal end of bend portion diverts from the longitudinal axis of the output end of the fiber core at a predetermined bend angle. A lens portion is disposed at the distal end of the bend portion concentrically with the longitudinal axis thereof and joined to the bend portion by a transition portion smoothly connecting the surface of the lens portion to the sides of the distal end of the bend portion. The lens portion is orbicular or spherical and is of a diameter greater than the diameter of the distal end of the bend portion. The resulting off-axis embodiment also transmits laser energy

in both the carrier and avalanche modalities of transmission and is particularly useful in applying laser energy to a broad section of tissue located on the interior of a body passageway immediately adjacent to the laser probe itself. In yet another embodiment of the off-axis orbicular embodiment of the invention, the length of the bend portion is typically in the range of about 0.5 millimeters to about 1.5 millimeters.

Additionally, the disclosed invention includes a method for making an end structure for the orbicular off-axis laser tip. In the method, the steps already described for producing an axially aligned orbicular end structure are first followed. Thereafter, a second portion of the length of the fiber core located intermediate and adjacent to the first portion and a third portion of the fiber core is heated rendering it molten. The second portion of the fiber core is then bend so that the longitudinal axis of the end thereof adjacent the first portion of the fiber core diverges at a predetermined angle from the longitudinal axis of the third portion of the fiber core. Heating in all instances may be accomplished through the use of an oxygen acetylene flame, an electric arc, high frequency radio signals, or the application of a laser.

In an alternate embodiment of the invention, a tip is provided for the end of an optical laser fiber core that is integrally formed therewith and has sides that flare

smoothly and without polishing abrasions from that first end to a terminus at a second end remote from the fiber core. The tip takes on a generally bulbous shape with sides that smoothly merge into the sides of the fiber core and terminate at the end remote from the fiber core in a flat surface or terminus disposed normal to the longitudinal axis of the fiber core. The diameter of the terminus is greater than the diameter of the fiber core itself. The tip may also be described as being generally hemispherical in shape. It may be located at either the input end of the fiber core to facilitate its optical coupling with the output of another, or at the output end thereof in order to produce a beam of outgoing laser energy of a diameter larger than that which would result from a naked optical fiber core of the same diameter.

In making the bulbous or hemispherical tip described above, the end of the optical fiber core is oriented in a vertical direction and a first portion of the length of the fiber core adjacent to that end is heated to render that first portion molten. Maintaining the vertical orientation of the fiber core, the heated first portion is permitted to assume a bulbous shape having smoothly flaring sides and a maximum diameter taken normal to the longitudinal axis of the fiber core that is greater than the diameter of the fiber core itself. Thereafter, the shape is cooled, and the end thereof remote from the fiber core is removed,

generally by polishing, to produce a flat surface or terminus disposed normal to the longitudinal axis of the fiber core.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to the specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope, the invention will be described with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 is an elevation view of one embodiment of a contact laser probe, including an optical waveguide, incorporating teachings of the present invention;

Figure 2 is an enlarged, detail elevation view of a first embodiment of the tip portion of the optical waveguide shown in Figure 1;

Figure 3 is an enlarged, detail elevation view of a second embodiment of the tip portion of the optical waveguide shown in Figure 1;

Figures 4A-4G are a sequence of illustrations depicting a method for manufacturing the tip portions of optical waveguides illustrated in Figures 2 and 3;

Figures 5A-5E illustrate alternative embodiments of a contact laser probes that incorporate teachings of the present invention;

Figures 6 is a third embodiment of a tip for an optical waveguide incorporating teachings of the present invention;

Figures 7A-7F are a sequence of illustrations depicting a method for manufacturing the tip portion of an optical waveguide illustrated in Figure 6;

Figure 8 is an enlarged, detail elevation view of a first embodiment of an off-axis end structure for an optical waveguide, such as is shown in Figure 1;

Figure 9 is an enlarged, detail elevation view of a second embodiment of an off-axis end structure for the optical waveguide shown in Figure 1;

Figure 10 is an enlarged, detail elevation view of a third embodiment of an off-axis end structure for the optical waveguide shown in Figure 1;

Figure 11 is a graph of the transmission percentage for off-axis structures such as those shown in Figures 8-10 varying as a function of the bend angle corresponding thereto;

Figures 12A-12G are a sequence of illustrations depicting a method for manufacturing the end structures of optical waveguides illustrated in Figures 8-10;

Figure 13 is an enlarged, detail elevation view of an axially aligned orbicular end structure for the optical waveguide shown in Figure 1;

Figure 14 is a schematic view of the lens portion of the end structure of Figure 13 illustrating selected optical characteristics thereof;

Figure 15 is an enlarged schematic view of the lens portion of the end structure of Figure 13 is in contact with tissue illustrating selected optical characteristics thereof; Figure 16 is an enlarged, detail elevation view of an off-axis orbicular end structure for the optical waveguide shown in Figure 1; and

Figures 17A-17E are a sequence of illustrations depicting a method for manufacturing the end structures of the orbicular optical waveguides illustrated in Figures 13 and 16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Shown in Figure 1 is a laser probe 10 for coupling to a medical laser (not shown) to be used in medical procedures. Laser probe 10 functions as an optical waveguide for precisely transmitting laser energy from the

medical laser to tissue to be treated according to prescribed medical procedures.

Toward this end, laser probe 10 includes a optical fiber composite 12 containing a core of optically transmissive material and having an input end 14 for receiving laser energy and an output end 16 remote therefrom for delivering the laser energy to the tissue to be treated. At input end 14 of optical fiber composite 12, laser probe 10 is provided with a fitting 18 having an input end 20 to be coupled to a medical laser to receive laser energy therefrom. The laser source coupled to laser probe 10 may include any of the medical lasers described above. A protective cap 22 is used to cover input end 20 of fitting 18 when laser probe 10 is not coupled to that medical laser source.

For the ease and convenience of a medical practitioner using laser probe 10, optical fiber composite 12 between input end 14 and output end 16 thereof is a flexible structure through which laser light is transmitted by internal reflectants within a fiber core concentrically surrounded by successive layers of other materials. A typical form of these layers will be discussed subsequently in relation to Figure 2. At output end 16 optical fiber composite 12 is encased in a cladding 24, generally comprised of needle stock. A fixed handle 26 is provided surrounding cladding 24 to afford an easy purchase on laser

probe 10 and to permit the laser energy transmitted therein to be directed to the correct tissue to be treated. The tip 28 of optical fiber composite 12, which protrudes from the end of cladding 24 remote from fitting 18, comprises the actual structure through which such a laser energy is applied to tissue. A protective sheath 30 is used to cover tip 28 when not in use.

A first embodiment of a tip 28 for the optical waveguide shown in Figure 1 is illustrated in enlarged detail in Figure 2. There, optical fiber composite 12 can be seen to be comprised of a fiber core 38 coaxially surrounded by a layer of hard cladding 40, which is in turn surrounded by a flexible reinforcing jacket 42. In medical situations, fiber core 38 is usually approximately 600 microns in diameter, although for special applications diameters of 200 microns, 400 microns, or 1000 microns are used. Fiber core 38 is generally composed of an optically transmissive material, such as quartz, silica, or a thermoplastic, for example polycarbonate. These materials not only readily transmit light, but are amorphus, contributing to their easy formation into the cylindrical shape of the typical fiber core. A fiber core comprised of these materials has a refractive index of about 1.45. Fiber core 38 is surrounded by a cladding 40 made of a polymer which has a lower refractive index than fiber core 38, thereby causing the interval reflectiveness of the

composite. Cladding 40 also protects fiber core 38 from environmental degradation, thus maintaining its strength. Finally, a reinforcing jacket 42 made of a plastic material, such as teflon or nylon, is added on the outside of hard cladding 40 to protect both hard cladding 40 and fiber core 38 from environmental conditions.

To achieve maximum effectiveness in transmitting laser energy through optical fiber composite 12 to a tissue to be treated in a medical procedure, the output end of fiber core 38 is provided with a focusing structure that directs emerging laser light into a pattern conducive to the medical procedure being undertaken.

Accordingly, in the present invention means are formed integrally with fiber core 38, and from the same material thereas, for narrowly focusing laser energy from output end 16 of optical fiber composite 12. As shown in Figure 2 by way of example and not limitation, tip 28 on the output end of fiber core 38 is rotationally symmetric and has sides 44 which taper smoothly from a first end 46 of tip 28 to a terminus 48 at a second end 50 of tip 28 remote from fiber core 38. Due to the manner in which tip 28 is formed, sides 44 thereof are free of polishing abrasions, thereby minimizing the diffusion of laser energy therethrough and directing an optimum amount of such energy from fiber core 38 through terminus 48 of tip 28.

Figure 48 comprises a flat surface disposed normal to the longitudinal axis of fiber core 38.

Where fiber core 38 is approximately 600 microns in diameter, the diameter D of terminus 48 will be in the range of about 10 microns to about 300 microns, depending upon the extent of focusing required in tip 28. The length L of tip 28 from first end 46 thereof to terminus 48 is typically in the range of about 1.5 millimeters to about 7.0 millimeters. If sides 44 of tip 28 are projected in a direction away from fiber core 38 to intersect at a point P, an apex angle A is defined having the vertex at point P and sides coincident with sides 44. In tip 28 the measure of apex angle A is in the range of about 4° to about 45° or more preferably in the range of about 9° to about 20°.

As seen in Figure 2, tip 28 has a terminus 48 which is a substantial fraction of the diameter of fiber core 38. When the length L of tip 28 is relatively short, then apex angle A has a measure in the upper portion of the range quoted therefor above.

This relative configuration is, however, subject to variation as evidenced by the appearance of a second embodiment of a tip 60 for laser probe 10 shown in Figure 1. There, the diameter D_1 of terminus 48 is relatively small compared to the diameter of fiber core 38, while the length L_1 of tip 60 is elongated relative to the same dimension of tip 28 in Figure 2. As a result the measure

of the apex angle A_1 formed by extending sides 44 away from optical fiber composite 12 to a point of intersection (not shown) is in the lower end of the range therefor mentioned above.

While the above ranges of physical dimensions in the inventive tip are based on a tip integrally formed with a fiber core having a diameter of about 600 microns, fiber cores for medical and other uses having both larger and smaller diameters will be enhanced when provided with tips formed according to the principals of the present invention. It should be understood that in such instances, appropriate adjustments to the dimensions of such inventive tips are to be expected and are considered to be within the scope of the present invention.

For example, utilizing a fiber core having a diameter of about 200 microns, tip lengths in the range of about 1.0 millimeters to about 1.5 millimeters with a terminus diameter in the range of about 10 microns to about 100 microns would be typical. The apex angle A in such devices would be in the range of about 4° to about 45°, or more preferably in the range of about 6° to about 20°. On the other hand, for a fiber core having a diameter of about 400 microns, tip lengths in the range of about 1.0 millimeters to 2.0 millimeters and terminus diameters in the range of about 10 microns to about 200 microns would be typical. Such devices would have an apex angle A with a measure in

the range of about 4° to about 45°, or more preferably in the range of about 11° to about 20°.

Alternatively, fiber cores with larger diameters can also be benefited by tips integrally formed therewith according to the teachings of the present invention. For example, a fiber core with a diameter of about 1000 microns would have a tip length in the range of about 1.5 millimeters to about 10.0 millimeters and a terminus diameter in the range of about 10 microns to about 700 microns. These devices would have an apex angle A having a measure in the range of about 4° to about 45°, or more preferably in the range of about 8° to about 20°.

The amount of laser energy that is transmitted out of tips 28 or 60 through terminus 48 thereof is determined by a number of factors. These include the amount of laser energy lost in fiber core 38 during transmission from input end 14 to output end 16 thereof, the shape of tips 28 or 60, the refractive index of the material of which those tips are made, and the refractive index of the tissue to which the tips are applied.

Assuming that a fiber core is made of quartz or silica, which has a refractive index of 1.45, and that fiber core 38 is not tapered as in Figures 2 and 3, but has a highly polished, flat end normal to the longitudinal axis of the fiber core 38, then only about 4 percent of the laser energy transmitted through fiber core will be

reflected backwards thereinto when the flat end is in air, which has a refractive index of 1.00. The remaining 96 percent of the laser energy will be transmitted into the air through the flattened end of the tip.

If, however, a focusing tip is used with the fiber core, the tip will have higher refractive index than the fiber core. For sapphire, the refractive index is 1.80; for diamond it is 2.60. In addition, an air gap will necessarily arise between the fiber core and the tip producing a double transmission interface for laser energy passing from the fiber core to and through the tip. Such laser energy will experience not only the above-described 4% backwards reflection when passing from the fiber core into the air gap, but will be further degraded by 8% in the case of sapphire and about 12% in the case of diamond when passing from that air gap into the tip itself.

Additionally it must be pointed out that for use in connection with living tissue, the refractive index of quartz or silica is very close to that of the material to which laser energy is ultimately to be delivered. This is not the case when a focusing tip of, for example, sapphire or diamond, is employed. Then, an additional transmission interface between the tip and the material to which laser energy is to be delivered further dissipate that energy. The amount of laser energy transmitted will also decrease

if the tip of the optical fiber core is rough, dirty or polished.

When formed according to the principles of the present invention, tips 28 and 60 are by contrast integral parts of fiber core 38. A principal advantage of this structure is the elimination of light losses that occur in prior art devices at the interface between the output end of an optical fiber core and the focusing structure or tip used therewith. The cause of these energy losses has been discussed above.

Tips 28 and 60 with a converging frustoconical shape and a terminus 48 that is normal to the axis of fiber core 38 focuses light down tapering sides 44 of tips 28 and 60 to emerge therefrom through interface 48. This is due to the smooth taper found in tips 28 and 60 and to the absence on sides 44 thereof of polishing abrasions. In addition, the absence of cladding 40 about the sides of tips 28 and 60 increases the internal reflectiveness of this portion of the laser probe. This effect arises because the refractive index of cladding 40 is less than that of the air surrounding the sides of tips 28 and 60 when cladding 40 has been removed therefrom. The resulting greater difference in refractive indexes causes laser energy traveling through tips 28 and 60 to be more readily reflected internally from the sides thereof than if cladding 40 were wrapped thereabout.

As a result, most laser energy transmitted through fiber core 38 is focused out of terminus 48 in the shape of a small diverging cone. Some of the laser energy will, nevertheless, reflected backup optical fiber composite 12 due to the mismatch between the refractive index of the material making up fiber core 38 as well as tip 28 or 60 and the refractive index of air. When tip 28 is placed in contact with a tissue, however, laser energy is coupled out of terminus 48 directly into the tissue with a minimum of reflection, as the refractive index of tip 28 closely resembles the refractive index of 1.45 ± 0.05 associated with the tissue.

Figures 4A-4G are a series of illustrations depicting the steps for making a tip for an optical waveguide, such as tip 28 of Figure 2 or tip 60 of Figure 3. Initially, Figure 4A shows an end 70 of optical fiber composite 12 dimensioned suitably for use in medical laser procedures and constructed in concentric layered fashion as illustrated in and described above in relation to Figures 2 and 3. To produce a tip for optical fiber composite 12, such as tip 28 of Figure 2 or tip 60 of Figure 3, reinforcing jacket 42 on the exterior thereof is removed to reveal the layer of hard cladding 40 thereunder as shown in Figure 4B. Thereafter, substantially all of hard cladding 40 thereby exposed is removed by precleaning to reveal a first portion 72 of optical fiber core 38 therewithin.

First portion 72 is located intermediate and adjacent to a second portion 74 and a third portion 76 at end 70 of fiber core 38. Precleaning may be effected by exposing the portion of cladding 40 overlying first, second, and third portions 72, 74, 76 respectively, of fiber core 12 to a flame, by mechanical stripping, or by washing the same portion of hard cladding 40 in an acetone bath followed by drying.

Optical fiber composite 12 is then placed in a jig comprised of a tube 78 made, for example, of metal or a ceramic and having an internal diameter that achieves a friction fit with the outer surface of optical fiber composite 12. The assembly is aligned vertically with end 70 of fiber core 38 pointing downwardly. A force F shown schematically in Figure 4D is applied to third portion 76 of fiber core 38 in a manner that places first portion 72 under tension in a direction parallel to the longitudinal axis thereof. Thereafter, heat H is applied to first portion 72 until first portion 72 is rendered molten.

The step of applying heat to first portion 72 can be accomplished by exposing first portion 72 to an electric arc. It is preferable that in creating an electric arc for this purpose in contrast to conventional equipment used in the field of optical fiber shaping, the equipment produce, not a focused electric arc, but one having a broad width relative to the length of first portion 72. In this manner

a substantial length, rather than a focused point, of fiber core 38 becomes heated. To do so it is necessary to appropriately configure the electrodes producing the electric arc and to appropriately position those electrodes relative to the first portion 72. Typically, this is accomplished by using electrodes which are elongated and parallel to the longitudinal axis of fiber core 38 and then positioning those electrodes on opposite sides of first portion 72 relatively remotely therefrom.

In addition heating can occur using an oxygen acetylene torch, radiant heat tunnels, high frequency radio signals, or laser energy itself as generated, for example, by a carbon dioxide laser. During the heating of first portion 72, metal tube 78 besides functioning as a jig to support optical fiber composite 12, also shields portions of optical fiber composite 28 remote from first, second, and third portions 72, 74, 76, respectively, from heat, thereby functioning as a cylindrical heat sink.

As first portion 72 becomes molten and ceases to be rigid, force F draws third portion 76 away from section portion 74 parallel to the longitudinal axis of fiber core 38. As a result, and as seen in Figure 4E, from the heated molten first portion 72 a shape 80 is produced having at the end thereof adjacent to second section 74 smoothly tapering sides and a lateral cross section decreasing with the distance from second portion 74. Typically a force F

of several grams is used in relation to a fiber core 38 having a diameter of 600 microns. Nevertheless, the size of force F may be varied to yield frustoconical shapes, such as shape 80, having different relative proportions. Metal tube 78 may be removed at any point after shape 80 has cooled.

After shape 80 has cooled, it is scored at a scoring point 83 located a pre-selected distance along shape 80 from second portion 74. Shape 80 is broken at scoring point 82 to form from the end thereof adjacent to second portion 74 a tip 28 for narrowly focusing laser energy transmitted through fiber core 38. The distance of scoring point 83 from second portion 74 will determine, not only the length, but the size of the terminus of any resulting tip.

Tip 28 is thus integrally formed with fiber core 38 from the same optically transmissive material of which fiber core 38 is made. The result is a tip 28 with a terminus 48 at the end thereof remote from optical fiber composite 12 which is a flat surface disposed normal to the longitudinal axis of optical fiber composite 12. Terminus 48 may be flattened by mechanical polishing and then fire polished to remove stress cracks at scoring point 82.

In the configuration of laser probe 10 shown in Figure 1, tip 28 and the portion of cladding 24 adjacent thereto extend a relatively short distance from handle 26

in alignment with the longitudinal axis thereof. Such an arrangement is conducive to a tool that may be utilized for general surgical purposes. Nevertheless, Figures 5A-5E depict alternate arrangements having special medical procedures in mind.

For example, Figure 5A illustrates a laser probe 86 in which the end of cladding 24 adjacent to tip 28 has been bent out of alignment with the longitudinal axis of handle 26 at an acute angle B_1. This enables the tool illustrated to be used in oral procedures.

In Figure 5B a laser probe 88 has cladding 24 that projects from handle 26 for an extended distance in the range of about 320 millimeters to 480 millimeters in alignment with the longitudinal axis of handle 26 and may thus be used for laparoscopic applications.

Figure 5C illustrates a laser probe 90 in which cladding 24 has been bent away from the longitudinal axis of handle 26 at angle B_2, but this occurs at a point closer to the end of handle 26 than occurs, for example, in laser probe 86 in Figure 5A. The portion of cladding 24 beyond the bend therein can be extended up to 90 to 100 millimeters so that the device shown in Figure 5C will function conveniently in nasal procedures.

In laser probe 92 shown in Figure 5D, cladding 24 has been bent twice in succession in compensating directions, so as to be offset from but parallel to the longitudinal

axis of handle 26. Such devices find application in neural surgery.

Finally, Figure 5E illustrates a laser probe 94 suitable for use in a laryngology procedure. In laser probe 94 cladding 24 has been angled away from the longitudinal axis of handle 26 at an angle B_3 greater than angle B_1 shown in Figure 5A or angle B_2 shown in Figure 5C. The portion of cladding 24 beyond the bend point may extend a distance of up to about 300 millimeters.

The frustoconical tip produced by the method of the present invention results in a contact laser probe having reduced transmission losses at the tip thereof. Because the tip and fiber core are made of the same material, and are integrally formed one with another, no transmission interface therebetween contributes to transmission losses and undesirable heat, as in known devices utilizing fiber cores and focusing tips distinct therefrom. Secondly, as the fiber core and the tip formed thereon are of the same material, and because the refractive index of optical cores is typically quite similar to that of tissue to be treated in medical laser procedures, laser energy dissipation at the interface between the tip and the tissue produces substantially less refraction losses than with medical laser probes having distinct fiber cores and tips. Finally, because the sides of the frustoconical tip of the present invention are not formed by polishing, they are

free of abrasions and do not tend to diffuse laser energy therethrough.

The reduced laser energy losses with the inventive tip eliminate the need for shielding for medical personnel and in endoscopic uses eliminates the need for auxiliary cooling systems and the safety risks associated therewith.

The result is an optical waveguide for efficiently and precisely transmitting laser energy from a medical laser to the tissue to be treated according to a medical procedure. Complicated methods of attaching the tip for the waveguide to the fiber core thereof are eliminated, as are the problem of loose or lost probe tips, and disposability of the device is enabled due to its reduced cost of manufacture.

The effectiveness of the tip configuration shown in Figures 2 and 3 in avoiding the build-up of heat have been confirmed by direct testing, which is reported below.

Example 1. A frustoconical tip such as that shown in Figures 2 and 3 having a length L of 7.0 millimeters and a diameter D for the terminus thereof of approximately 100 microns was tested to determine the percent of laser energy transmitted therethrough into water. Each tip was subjected to a maximum power of 6.6 watts for various numbers of exposures at selected times and was then inspected for any adverse effects, such as darkening,

chipping, or deformation due to heat. The following test results were observed:

TABLE I

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	89	9.0	2	None
2	90	9.0	2	None
3	81	9.0	2	None
4	86	9.0	2	None
5	89	9.0	2	None
6	85	9.0	2	None
7	84	9.0	2	None
8	93	0.5	6	None*
9	92	2.5	6	None
10	88	9.0	1	None

*Fiber tip chipped due to being dropped on floor. Test continued.

Mean % Transmission in water: 88%

Power Source: Visible multiline argon laser, 6.6W maximum power.

Measurement: Laserguide Model 2015 integrating sphere power meter calibrated for visible multiline argon.

Two advantageous results are apparent in relation to prior art devices such as sapphire tips used in combination with conventional fiber cores. First, the mean

transmission percentage is much improved in relation to such prior art devices. Secondly in such prior art devices substantial quantities of laser energy are dissipated as heat which would otherwise be expected under the circumstances in which the above test was conducted to result in tip destruction.

Example 2. Subsequently, a probe tip of frustoconical configuration constructed according to the teachings of the present invention having a tip length L in the range of about 1.5 to 2.0 millimeters and a diameter D at the terminus thereof of about 100 microns was tested for percent power transmission in water and subjected to a maximum power test at 8.4 watts for various numbers of various exposure times. The results observed appear below:

TABLE II

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	90	20	2	None
2	90	20	2	None
3	88	20	2	None
4	88	20	2	None
5	90	20	2	None
6	91	20	2	* None

(Continued on following page)

TABLE II
(continued)

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
7	88	20	2	None
8	91	20	2	None
9	91	20	2	None
10	91	20	2	None
11	90	20	2	None
12	90	20	2	* None
13	91	20	2	None
14	91	20	2	None
15	90	60	2	None
16	90	60	2	None
17	88	120	2	None
18	90	180	2	None

*Fiber showed slight chip prior to testing. These fibers were not rejected to see how slight damage would affect transmission.

Mean Transmission Percent in Water: 90%

Power Source: Visible multiline argon laser, 8.4W maximum power.

Measurement: Laserguide Model 2015 integrating sphere power meter calibrated for visible multiline argon; Lexel power meter.

Once again, in contrast to composite prior art devices in which a tip and a fiber core having differing refractive indices are used in combination, the inventive tips for which test data is recorded above had a advantageously high mean transmission percentage in water of 90 percent, and no visually detectable evidence of heat damage was observed.

Example 3. In an additional test, a tip, such as that illustrated in Figures 2 and 3 having a length L in the range of about 1.5 to 2.0 millimeters and a diameter D at the terminus thereof of about 100 microns was tested at 8.5 watts for transmission percent in water. In addition each tip involved was tested at the extremely high power of 75 watts for a single exposure of 20 seconds and inspected for visual evidences of heat damage. The results are shown below:

TABLE III

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	85	20	1	None
2	85	20	1	None
3	87	20	1	None
4	88	20	1	None
5	89	20	1	None
6	88	20	1	None

TABLE III
(continued)

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
7	87	20	1	None
8	85	20	1	None
9	88	20	1	None
10	88	20	1	None
11	87	20	1	None
12	87	20	1	None
13	87	20	1	None
14	87	20	1	None
15	86	60	1	None
16	87	60	1	None
17	88	120	1	None

Mean Transmission Percent in Water: 87%

Power Source: Quantronix 117 laser, maximum power used 75W.

Measurement: Coherent power meter.

An advantageously high mean transmission percent in water of 87 percent was observed. Despite power exposures which would have destroyed prior art composite tip-and-fiber core combinations, the inventive tips tested above were undamaged. Figure 6 illustrates a third embodiment of a tip 100 embodying teachings of the present invention. Tip 100 can be seen to be integrally formed with fiber core

38 of an optical fiber composite 12 configured as illustrated and described previously in relation to Figures 2 and 3. Tip 100 is rotationally symmetric and radially coextensive at a first end 102 thereof with fiber core 38. In contrast to the frustoconical embodiments illustrated in Figures 2 and 3, however, tip 100 has sides 104 that flare smoothly from first end 102 to an enlarged terminus 106 at second end 108 remote from fiber core 38. Similarly, however, to the two frustoconical embodiments 28 and 60 shown in Figures 2 and 3, respectively, the outer surface of sides 104 of tip 100 are free from polishing abrasions. This is due to the manner to be described below in which tip 100 is formed and results in the minimizing of the diffusion of laser energy through sides 104.

In general terms, tip 100 assumes a bulbous shape having a maximum diameter D_3 taken normal to the longitudinal axis of fiber core 38 which is greater than the diameter of fiber core 38 itself. The bulbous shape terminates at second end 108 in a flat surface or terminus 106 disposed normal to the longitudinal axis of fiber core 38. Alternatively, tip 100 can be described as comprising a generally hemispherical shape, the planar surface of which functions as the terminus of tip 100. For a fiber core 38 having a diameter of approximately 600 microns, the diameter D_3 of terminus 106 of tip 100 is in the range of from about 600 microns to about 800 microns.

Tip 100 exhibits advantageous properties. First, if placed at the output end of an optical fiber core and used in a non-contact maneuver to deliver laser energy to tissue or another material, tip 100 serves to produce a pattern of laser energy discharge corresponding to an optical fiber core having a diameter larger than the optical fiber core with which tip 100 is integrally formed. This result has been achieved previously only through the use of focusing structures distinct from the optical fiber core itself, and consequently afflicted by the drawbacks inherent therein as described above.

In addition, however, it has been found that in coupling one optical fiber core to another it is necessary that the end of the fiber core from which laser energy is being transmitted be smaller than the input end of the receiving fiber core optically coupled thereto. Where a series of couplings are required, each successive section of fiber core is, therefore, necessarily larger in diameter than that which preceded it. In the alternative each fiber core output end has been tapered by polishing it into a terminus having a diameter smaller than the fiber to which it is attached.

Both alternatives have disadvantages. In the former, the successive enlargement of fiber optic cores leads to a pattern of laser energy discharge which is broader than and more diffused than the laser output that would have been

achievable from the end of the first fiber core in the series. In the latter instance, the polished sides of each tapered output end gives rise to the diffusion of laser energy due to the polishing abrasions thereon. Tip 100 avoids these problems in coupling situations permitting successive sections of spliced fiber core to have the same dimension.

It should be noted that use of a slightly tapered frustoconical form of the invention, such as that shown in Figures 2 and 3, can similarly advantageously permit the splicing of successive sections of fiber core each having the same diameter. Each thusly tapered tip at the output end of each section of a fiber core focuses the laser energy transmitted therethrough into a terminus which has a diameter less than that of the fiber to which the tip is formed or the input end of the successive fiber core to be optically coupled thereto. The absence of polishing abrasions on the surface of the tapering sides of the frustoconical tip reduces substantially the diffusion of laser energy through those sides at each splicing juncture.

Figures 7A through 7F are a series of illustrations depicting a method by which to form a tip, such as tip 100, at the end of an optical fiber core. Again as in Figure 4A, the process begins with an optical fiber composite 12 concentrically layered in the manner illustrated and described in Figure 6. Reinforcing jacket 42 is first

removed from end 70 of optical fiber composite 12 to reveal hard cladding 40 thereunder, as shown in Figure 7B. Thereafter, precleaning is conducted in which hard cladding 40 is removed from overlying a first portion 120 of fiber core 38 located at end 70 thereof to produce the configuration shown in Figure 7C. Precleaning in this instance can take any of the forms already described in relation to Figures 4A-4G.

Optical fiber composite 12 is then secured in a jig comprising a metal tube 78 capable of effecting a friction fit with the outside surface of optical fiber composite 12, and end 70 thereof is oriented in a vertical direction. Heat H is then applied to first portion 120 to render first portion 120 molten. The heating of first portion 120 can be accomplished in any of the manners of heating described in relation to Figures 4A-4G. Maintaining the vertical orientation of fiber core permits the heated first portion 120 to assume a bulbous shape 122 shown in Figure 7E as having smoothly flaring sides 104 and a maximum diameter taken normal to the longitudinal axis of fiber core 38 that is greater than the diameter of fiber core 38 itself. Bulbous shape 122 is then cooled and the end 124 thereof remote from fiber core 38 is removed to produce a flat surface or terminus 106 normal to the longitudinal axis of fiber core 38.

In Figure 8 is shown a first embodiment of an off-axis end structure 130 capable of focusing laser energy at an angle to the longitudinal axis of the output end of an optical fiber. With this capacity, end structure 130 is of particular utility in focusing laser energy emerging from the output end of a medical laser probe waveguide on the wall of a bodily passageway in which the waveguide is disposed. End structure 130 can be seen to be integrally formed with fiber core 38 of an optical fiber composite 12 configured as illustrated and described previously in relation to Figures 2 and 3.

According to one aspect of the present invention, means are provided for narrowly focusing laser energy from fiber core 38 onto portions of tissue off-set laterally from longitudinal axis Y-Y thereof. As shown by way of example and not limitation in Figure 8, off-axis end structure 130 comprises a generally cylindrical bend portion 132 and a tip 134 formed on the distal end thereof. Bend portion 132 has a proximal end radially coextensive with fiber core 38 at the output end thereof. The longitudinal axis Z-Z of bend portion 132 at the distal end thereof, which is also the longitudinal axis of tip 134, diverts from longitudinal axis Y-Y of the output end of optical fiber core 38 at a predetermined bend angle B.

Tip 134 is generally rotationally symmetric and radially coextensive at a first end 136 thereof with bend

portion 132. Tip 134 has sides 138, 140 that taper smoothly from first end 136 to a terminus 142 that is a flat surface disposed normal to the plane of bend portion 132 and parallel to longitudinal axis Y-Y of fiber core 38 at the output end thereof. The terminus, such as terminus 142 in the present invention, need not, however, assume this orientation exclusively. The outer surface of sides 138, 140 are free from polishing abrasions due to the manner to be described below in which off-axis end structure 130 is formed. This results in the minimizing of the diffusion of laser energy through sides 138, 140.

In general, it has been discovered that laser energy projected along optical fiber core 38 has a tendency to be reflected off the inside of sides 138, 140 so as to be directed through tip 134 and out thereof by way of terminus 142. Surprisingly, only minor amounts of laser energy are refracted out of tip 134 through side 140 on the surface of tip 134 adjacent the curve outer surface of bend portion 132. This advantageously leaves side 140 of tip 134 cool enough to not damage tissue with which it makes inadvertent contact. When optical fiber 12 is disposed inside a tubular body passageway, it is thus possible using bend structure 130 to focus laser energy on the walls of such a passageway in the immediate vicinity of the output end of fiber core 38, and conduct orthoscopic laser procedures without the need to use bulky and

expensive auxiliary equipment. Even more significantly, however, this can be accomplished efficiently, without generating excessive and potentially dangerous heat.

It has also been found that if pointed second end 144 of tip 134 is pressed against or into a bodily tissue, laser energy exits therefrom and enters that tissue through side 138 of tip 134, which is adjacent to the inner surface 146 of bend portion 132, enhancing the cutting capacity of end structure 130 when used in the contact mode.

As will be illustrated in relation to Figure 11, the measure of bend angle B can range upwardly to approximately 90°, but preferably is in the range from approximately 15° to approximately 60°, or more preferably in the range from approximately 25° to approximately 45°.

Due to the manner in which bend structure 130 is formed, the exterior sides thereof are free of polishing abrasions, thereby minimizing the diffusion of laser energy therethrough and directing an optimum amount of such energy from fiber core 38 through terminus 142 of tip 134. While end structure 130 will to a degree transmit laser energy through side surface 140 thereof when side 140 encounters tissue, nevertheless, the degree of such laser energy transmission through side 140 is relatively small compared to that observed through side 138. Thus, cutting strokes with end structure 130 are best made utilizing bend

portion 132, if made in a direction backwards along longitudinal axis Y-Y of optical fiber 38.

Where fiber core 38 is approximately 600 microns in diameter, the diameter D of terminus 142 will be in the range of approximately 10 microns to approximately 300 microns, depending upon the extent of focusing required in tip 134. The length L_2 of tip 134 from first end 136 thereof to terminus 142 is typically in the range of approximately 1.5 millimeters to approximately 7 millimeters. The length M of fiber core 38 utilized in creating bend portion 132 ranges from approximately 0.5 millimeters to approximately 1.5 millimeters. If sides 138 and 140 of tip 134 are projected in a direction away from fiber core 38 to intersect at a point Q, an apex angle A_2 is defined having a vertex at point P and sides coincident with sides 138, 140. In tip 134 the measure of apex angle A_2 is in the range of about 4° to about 45°, or more preferably in the range of about 9° to about 20°.

This relative configuration is, however, subject to variation as evidenced in Figure 9 by the appearance of a second embodiment of an end structure 150 for probe 10 shown in Figure 1. There, it will be appreciated that the measure of bend angle B_1 is relatively less than the measure of bend angle B shown in Figure 8. End structure 150 comprises a bend portion 152 and a tip 154 located on the distal end thereof. The length L_3 of tip 154 is

substantially greater than that of tip 134, and terminus 155 at the end of tip 154 is a flat surface disposed normal to the longitudinal axis Z_1-Z_1 of tip 154 having a diameter D_3 less than the diameter D_2 of terminus 142 in Figure 8. Tip 154 as an apex angle A_3 that is less than the corresponding dimension in Figure 8.

Shown in Figure 10 is a third embodiment of an end structure 160 embodying teachings of the present invention capable of focusing laser energy from fiber core 38 in a direction off-set from longitudinal axis Y_2-Y_2 thereof. The bend angle B_2 at which this can be effected is more severe in Figure 10 than in either of Figures 8 or 9 ranging upwardly to about 90°. As seen in Figure 10, end structure 160 comprises a bend portion 162 and a tip 164 on the distal end thereof having a longitudinal axis Z_3-Z_3 and an apex angle A_4.

Figure 11 communicates some sense of the relative transmission capacity of an off-axis end structure, according to the present invention. There appears a curve of transmission efficiency plotted on a graph against the measure of the bend angle associated therewith. Conventionally in straight laser probes, an 80% transmission efficiency is considered in the prior art to be a normal range of transmission. As can be seen by the graphs shown in Figure 11, bend angle measures from approximately 0° to approximately 25° satisfy this

criteria, despite the bending of laser energy direction achieved in the process. At a reduced transmission percentage of 75% to 80%, the range of the measure of the bend angle involved can be as high as approximately 50°. Ultimately, however, it is considered to be within the scope of the present invention when bend angles B are employed ranging upwardly to approximately 90°. The use of tips with even larger bend angles is conceivable, although drops in transmission efficiency can be expected above about 90°.

Figures 12A-12G are a series of illustrations depicting the steps for making an end structure for an optical waveguide, such as those shown in Figures 8-10. Initially, Figure 12A shows an end 70 of optical fiber composite 12 dimensioned suitably for use in medical laser procedures and constructed in concentric layered fashion as illustrated in and described above in relation to Figures 2 and 3. To produce an inventive end structure for optical fiber composite 12, reinforcing jacket 42 on the exterior thereof is removed to reveal the layer of hard cladding 40 thereunder as shown in Figure 12B. Thereafter, substantially all of hard cladding 40 thereby exposed is removed by precleaning to reveal a first portion 72 of optical fiber core 38 therewithin. A first portion 72 is located intermediate and adjacent to a second portion 74 and a third portion 76 at end 70 of fiber core 38.

Precleaning may be effected by exposing the portion of cladding 40 overlying first, second, and third portions 72, 74, 76, respectively, to a flame, by mechanical stripping, or by washing in an acetone bath followed by drying.

A force F_3 shown schematically in Figure 12C is applied to third portion 76 in a manner that tends to bend first portion 72. Thereafter, heat H is applied to first portion 72 until first portion 72 is rendered molten.

The step of applying heat to first portion 72 can be accomplished by exposing first portion 72 to an electric arc. As discussed above, it is preferable that in creating an electric arc for this purpose the equipment involved produce, not a focused electric arc, but one having a broad width relative to the length of first portion 72. In this manner, a substantial length, rather than a focused point of fiber core 38 becomes heated. Heating can occur in other means described above.

Next, a tip is formed from first portion 76 by which to narrowly focus laser energy from a medical laser. Initially a first section 166 of the length of third portion 76 is heated to render first section 166 molten. First section 166 is located intermediate and adjacent to second section 168 and third section 170 adjacent to first portion 172 of fiber core 38. A force F_4 shown schematically in Figure 12D is then applied to second

section 68 parallel to the longitudinal axis of third portion 176 to draw first section 166 into an hourglass shape 171 shown in Figure 12E. Thereafter, the hourglass shape is scored at point 172, broken thereat, and polished in order to produce a terminus 174 that is both normal to the plane defined by the event version of first portion 172, while being parallel to the longitudinal axis Y_3-Y_3 of fiber core 38.

The effectiveness of the off-axis end structure shown in Figures 8-9 in diverting laser energy in an off-axis direction while avoiding the build-up of heat has been confirmed by direct testing, which is reported below.

<u>Example 4.</u> An end structure such as that shown in Figures 8-10 having a bend angle having a measure of approximately 45° was tested to determine the percent of laser energy transmitted therethrough into water. Each tip was subjected to a maximum power of 100 watts for a single exposure for the time indicated and was then inspected for any adverse effects, such as darkening, chipping, or deformation due to heat. The following test results were observed.

TABLE IV

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	70	20	1	None
2	77	20	1	None
3	72	20	1	None
4	74	20	1	None
5	71	20	1	None
6	76	20	1	None
7	77	20	1	None
8	79	20	1	None
9	75	20	1	None
10	75	20	1	None

TABLE IV
(continued)

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
11	78	20	1	None
12	79	20	1	None
13	76	20	1	None
14	78	20	1	None
15	77	20	1	None
16	78	20	1	None
17	76	20	1	None
18	77	20	1	None
19	78	20	1	None
20	78	20	1	None
AVERAGE:	76.05%			

Mean Transmission Percent in Water: 76%

Power Source: Quantronix 118 model YAG Laser Serial No. 688.

Measurement: Laserguide Model 90-2030.

First, it is noteworthy that the mean transmission percentage is much improved in relation to prior art devices for focusing laser energy laterally of the tip of a contact laser probe. Secondly, in such prior art devices, substantial quantities of laser energy are dissipated as heat, which would otherwise be expected under

the circumstances in which the above test was conducted to result in tip destruction.

Example 5. Subsequently, an end structure was complete by having a tip of frustoconical configuration and being constructed according to the teachings of the present invention and having a bend angle of approximately 30° was tested for percent power transmission in water and subjected to a maximum power test at 100 watts in a single test under the conditions listed. The results observed appear below:

TABLE V

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
1	80	20	1	None
2	84	20	1	None
3	80	20	1	None
4	82	20	1	None
5	81	20	1	None
6	80	20	1	None
7	81	20	1	None
8	83	20	1	None
9	82	20	1	None
10	82	20	1	None

(continued on next page)

TABLE V
(continued)

Sample	Percent Transmission (in water)	Exposure Time (in seconds)	No. of Exposures	Tip Visual Changes
11	81	20	1	None
12	81	20	1	None
13	83	20	1	None
14	82	20	1	None
15	81	20	1	None
16	83	20	1	None
17	80	20	1	None
18	82	20	1	None
19	81	20	1	None
20	82	20	1	None
AVERAGE:	81.55%			

Mean Transmission Percent in Water: 82%

Power Source: Quantronix 118 YAG Laser Serial No. 688

Measurement: Laserguide Model 2030, Serial No. 002

Once again, in contrast to composite prior art devices in which a tip and a fiber core having different refractive indices are used in combination, the inventive tips for which test date is recorded above had an advantageously high mean transmission percentage in water of 82%. Literally no visually detectable evidence of heat damage was observed.

Thus, it can be seen that the off-axis embodiment of the inventive contact laser probe tip permits surgery to be performed orthoscopically on the walls of bodily passageways through which the laser probe is advanced to reach the surgery site. The risks associated with stray laser energy causing potential injury to healthy portions of the bodily passageway, or of damage thereto due to heat, are reduced over known devices. The simplicity and reliability of the equipment is also enhanced.

Figure 13 illustrates yet another embodiment of an end structure 180 embodying additional teachings of the present invention in order to deliver laser energy from a medical laser to tissue to be treated according to a medical procedure while maintaining high transmission efficiency. In contrast to the tapered axially aligned tips 20 and 60 of Figures 2 and 3, respectively, and the off-axis tapered tips 130, 150, and 160 of Figures 8, 9, and 10, respectively, end structure 180 does not focus laser energy into an intense, localized pattern. Instead, end structure 180 transmits laser energy from optical fiber 12 onto a large surface area of tissue. Having this capacity, end structure 180 is ideally suited for rapidly vaporizing large volumes of tissue with which it is brought into contact. Each structure 180 has additionally been found to be effective in producing homeostasis in blood vessels severed in the process.

In common, however, with the earlier described tapered laser probe tips and end structures, end structure 180 is disposed at the output end 182 of fiber core 38 and is integrally formed therewith from the same optically transmissive material. Ideally that optically transmissive material has an index of refraction similar to that of the tissue to be treated utilizing end structure 180. Materials which have functioned satisfactorily in this role include, quartz, silica, and certain thermoplastic materials. Typically, fiber core 38 is surrounded by a flexible jacket of hard cladding 40 which terminates short of output end 182 of fiber core 38. Exterior to hard cladding 40 is reinforcing jacket 42.

Structurally, end structure 180 comprises a lens portion 184 which is disposed at output end 182 of fiber core 38 in a concentric relationship with the longitudinal axis Y_3-Y_3 thereof. As illustrated in the embodiment shown in Figure 13, lens portion 184 takes on an orbicular or spherical shape having a surface 186 and a diameter E_1 greater than the diameter D_2 of fiber core 38. End structure 180 also comprises, however, a transition portion 188 having a surface 190 which smoothly connects the surface 186 of lens portion 184 with the exterior of fiber core 38. Due to the manner in which end structure 180 is fabricated from the material of fiber core 38, the surface 186 of lens portion 184 and the surface 190 of transition

portion 188 are free of scratches and polishing abrasions which would give rise to the transmission of laser energy through those surfaces and the generation of unwanted heat thereat. In this manner, the physical nature of end structure 180 is specifically designed to transmit laser energy directly to the tissue at a surgical site while maintaining high transmission efficiency and avoiding the production of troublesome heat.

Typically, depending upon the size of the optical fiber 38 utilized, the diameter E_1 of lens portion 84 is in the range from about 0.3 millimeters to about 5.0 millimeters for fiber cores 38 having diameters D_2 in the range from about 1.9 millimeters to about 4.5 millimeters, respectively. More narrowly, however, the diameter E_1 of lens portion 184 is in the range from about 0.6 millimeters to about 3.0 millimeters where the diameter D_2 of fiber core 38 is in the range from about 0.4 millimeters to about 3.0 millimeters, respectively,. More preferably therewithin lens portion 184 has a diameter E_1 in the range about 0.8 millimeters to about 2.5 millimeters, where the diameter D_2 of fiber core 38 is in the range from about 0.6 millimeters to about 2.0 millimeters. For example, where the diameter D_2 of fiber core 38 is about 1.0 millimeters, an appropriate diameter E_1 for lens portion 184 would be about 1.2 millimeters. With a smaller fiber core 38 as, for example, a fiber core 38 having a diameter D_2 that is about 0.6

millimeters, the anticipated appropriate diameter E_1 of lens portion 184 would be about 0.8 millimeters.

The advantageous optical features of end structure 180 will be explored in relation to Figures 14 and 15 taken together.

According to one aspect of the present invention, end structure 180 comprises a means for focusing a portion of the laser energy delivered from output end 182 of fiber core 138 through a fast focal point align with the longitudinal axis of $Y_3 - Y_3$ of fiber core 38 at output end 182 thereof. As used herein and in the appended claims, this modality of laser energy transmission from end structure 180 will be referred to as the carrier mode of laser energy transmission, and the portion of the laser energy focused through a fast focal point will be referred to as a "second portion" of that energy.

As shown in Figure 14, a plurality of rays W_1, W_2, W_3, W_4, and W_5 of laser energy are delivered from output end 182 of optical fiber 38 into transition portion 188 and therethrough into lens portion 184. These rays of laser energy are possessed of various degrees of alignment with longitudinal axis Y_3-Y_3 of fiber core 38. Some of the rays of laser energy, such as the rays W_2 and W_3 of laser energy, are of a very low order mode, traveling closely parallel to longitudinal axis Y_3-Y_3. Absent any severe kinking in optical fiber 12, it can be expected that low order rays of

laser energy, such as laser energy rays W_2 and W_3, will continue to maintain a low order mode throughout the length of the fiber and during the passage across lens portion 184 of end structure 180.

Low order rays of laser energy, such as laser energy rays W_2 and W_3 impact the surface 186 of lens portion 184 remote from fiber core 38 in a circular region having in the view of Figure 14 extreme points J and K. The surface 186 of lens portion 184 located between points J and K then functions as a positive lens to focus such low order laser energy rays through a fast focal point X. The second portion of the laser energy thus delivered through fast focal point X accordingly corresponds to low order rays of laser energy, such as rays W_2 and W_3. Fast focal point X will fall on longitudinal axis Y_3-Y_3, if end structure 180 between points J and K is symmetric about that longitudinal axis. Minor asymmetrical irregularities in end structure 180 are not, however, considered to depart from the spirit of the present invention, in that it is not the positioning of fast focal X that gives end structure 180 its utility. While the existence of a fast focal X is a physical parameter useful in describing end structure 180, it is another aspect of the present invention which gives end structure 180 its major utility for rapidly vaporizing large volumes of tissue during a medical procedure.

Thus, according to yet another aspect of the present

invention, end structure 180 comprises means for internally star-reflecting in a region of multi-directional laser energy a portion of the laser energy delivered from output end 132 of fiber core 38. As used herein and in the appended claims, the portion of the laser energy thus internally reflected in the region of multi-dimensional laser energy in lens portion 184 corresponds to low order rays of energy delivered from output end 182 of fiber core 38. Again, as seen in Figure 14 a number of high order rays of laser energy W_1, W_4, and W_5 are delivered from output end 182 of fiber core 38 into end structure 180. These high order rays of laser energy do not normally impact the surface 186 of lens portion 84 between points J and K so as to be focused through fast focal point X. Instead, high order rays of laser energy, such as laser energy rays W_1, W_4, and W_5 are initially reflected internally off of the abrasion-free surfaces 186 of lens portion 184 and 190 of transition portion 188. These high order rays of laser energy continue thereafter to be reflected internally and successively about lens portion 184 in a star-reflecting pattern which develops within lens portion 184 a region of multi-directional laser energy which is not normally transmitted therefrom in any substantial degree. Some of the star-reflecting, multi-directional laser energy will in due course impact the surface 186 of lens portion 184 between points J and K at an appropriate angle to become

focused with high order rays, such as laser ray W_3, through fast focal point X. Other individual rays of the star-reflecting, multi-directional laser energy in lens portion 184 will occasionally escape from end structure 180 backwards into output end 182 of fiber core 38. Nevertheless, these losses of the star-reflecting, multi-directional laser energy are minor when compared with the energy contained in high order rays of laser energy arriving on a continuing basis through transition portion 188 from output end 182 of fiber core 38.

Thus, while transmitting a portion of the laser energy delivered from output end 182 of fiber core 38 in a carrier mode of transmission, another portion of the laser energy delivered from output end 182 of fiber core 38 is internally star-reflected to form in lens portion 84 a region of multi-directional laser energy having as its boundary the surface 186 if lens portion 184. A typical pattern of plural internal star-reflections is shown in Figure 14 for laser energy ray W_1. The path of travel of the successive reflections of other high order rays of laser energy, such as rays W_4 or W_5, has for the sake of clarity been omitted. Nevertheless, a similar series of almost endless internal reflections will occur in each instance for the high order rays illustrated and for each successive high order ray of laser energy delivered from output end 182 of fiber core 38. The containment of the

multi-directional laser energy in lens portions 184 is dependent upon two factors: the absence of abrasions on surface 186 of lens portion 184, and the presence on surface 186 of lens portion 184 of no material with an index of refraction closely matched to the index of refraction of the optically transmissive material of which end structure 180 is comprised. When no such index matching material is in contact with surface 186 of lens portion 184, end structure 180 operates in the carrier mode of transmission passing but a portion of the laser energy emerging from output end 182 of fiber core 38 by focusing such laser energy through fast focal point X.

Nevertheless, as illustrated in Figure 15, end structure 180, which has already been identified as functioning as a means for internally star-reflecting another portion of the laser energy delivered from output end 182 of fiber core 38, also functions as a means for selectively directing that multi-directional laser energy in lens portion 184 through surface 186 thereof at such portions of surface 186 as contact an organic tissue or fluid exhibiting a close refractive index match with fiber core 38.

As shown in Figure 15, end structure 180 has been advanced into contact with an area of tissue 192, whereby tissue 192 contacts surface 186 of lens portion 184 at the arcs thereof disposed between points M and N and between

points P and Q. The index of refraction for tissue 192 is similar to that for fiber core 138 and end portion 180. Under such circumstances, the second portion of the laser energy delivered from fiber core 38 that is internally star-reflected within lens portion 184 no longer continues to be reflected in this manner whenever that energy encounters surface 186 of lens portion 184 between points M and N or between points P and Q. Instead, the multi-directional laser energy in lens portion 84 is transmitted into tissue 192 wherever that tissue contacts surface 186. Thus, as the multi-directional laser energy in lens portion 184 encounters surface 186 between points M and N, rather than being reflected therefrom, it is directed through surface 186 into tissue 192. In Figure 15, this component of the multi-directional laser energy in lens portion 184 has been designated by W_{MN}. Correspondingly, a component of the multi-directional laser energy in lens portion 184 is directed into tissue 192 through surface 186 between points P and Q, and has been designated in Figure 15 as W_{PQ}. The laser energy W_{MN} and W_{PQ} directed into tissue 192 is not focused into a narrow beam, but rather impacts a broad portion of the surface of tissue 192 and is ideally suited for rapid vaporization of substantial volumes of such tissue.

The portions of surface 186 of lens portion 184 which are not contacted by tissue 192, however, continue to

internally star-reflect high order rays of laser energy. In Figure 15 this would include, for example, the portion of surface 186 between points N and P and the portions of surface 186 between fiber core 38 and points M and Q, respectively. There, high order laser energy rays continue to be internally reflected into the region of multi-directional laser energy bounded by surface 186. Thus, by way of example, laser energy ray W_1 is shown internally star-reflecting from surface 186 between points N and P thereon as well as from surface 186 between point Q and fiber core 38.

It should be noted that while an avalanche mode of transmission is shown occurring in Figure 15, the carrier mode of transmission of low order rays of laser energy continues, directing such rays as impact surface 186 between points J and K through fast focus X. Should tissue 192 contact surface 186 between points J and K thereon, the laser energy normally transmitted therethrough in the carrier mode of transmission would then enter tissue 192 for the purpose of vaporizing same. Such a situation, while not illustrated explicitly in Figure 15 can easily be visualized.

Figure 16 illustrates yet another embodiment of an end structure 200 embodying teachings of the present invention, including those discussed already in relation to end structure 180 shown in Figure 13. End structure 200 is

integrally formed on output end 182 of fiber core 38 so as to have sides free of scratches and polishing abrasions, and thereby to be capable of transmitting laser energy delivered from output end 182 of fiber core 38 while maintaining high transmission efficiency. End structure 200 comprises a generally cylindrical bend portion 202 having a proximal end 204 coextensive with output end 182 of fiber core 38 and a distal end 206 opposite therefrom. The longitudinal axis Z_3-Z_3 of bend portion 202 at distal end 204 thereof diverts from the longitudinal axis Y_4-Y_4 of output end 82 of fiber core 38 at predetermined bend angle B_3. Due to the same optical limitations discussed in relation to the off-axis end structures 130, 150, and 160 illustrated in Figures 8, 9, and 10, respectively, bend angle B_3 can assume a range from about 0° to about 90°. More particularly, however, the range of bend angle B_3 is from about 15° to about 60° or, more narrowly, from about 30° to about 45°.

End structure 200 also comprises a lens portion 208 disposed at distal end 206 of bend portion 202 concentrically with longitudinal axis Z_3-Z_3 thereof. A transition portion 210 having surfaces 212 smoothly connects the surface 214 of lens portion 208 to bend portion 202. As in end structure 180 shown in Figure 13, lens portion 208 is orbicular or spherical, having a diameter E_2 that is greater than the diameter D_3 of fiber

core 38 and bend portion 202. The size of the diameter E_2 of lens portion 208 varies primarily according to the diameter D_3 of fiber core 38 in the same range as stated in relation to the diameter E_1 of lens portion 184 illustrated in Figure 13. The length M_1 of bend portion 202 is found generally in the range of from about 0.5 millimeters to about 1.5 millimeters.

In operation, as discussed previously in relation to the embodiments illustrated in Figures 8, 9, and 10, laser energy from fiber core 38 is redirected by bend portion 202 in order to enter transition portion 210 and lens portion 208 at an angle which generally diverges from longitudinal axis Y_4-Y_4 of fiber core 38 by the predetermined bend angle B_3. End structure 200 functions as a means for focusing a portion of the laser energy from fiber core 38. As in the case of end structure 180 of Figure 13, low order rays of laser energy are transmitted through the tip 216 of lens portion 208 and focused through a fast focal point aligned with longitudinal axis Z_3-Z_3 of distal end 206 of bend portion 202. Thus, a second portion of the laser energy delivered through output end 182 of fiber core 38 corresponding to low order rays of laser energy is transmitted through end structure 200 in a carrier mode of transmission. In the manner already discussed in relation to Figures 14 an 15, however, end structure 200 also functions as a means for internally star-reflecting in a

region of multi-directional laser energy a first portion of the laser energy delivered from fiber core 38 and for selectively directing that multi-directional laser energy in an avalanche mode of transmission through the boundary of that region at such portions thereof as contact a biological tissue or fluid having an index of refraction matching that of fiber core 38. Once laser energy from fiber core 38 has been redirected by bend portion 202 of end structure 200, the mechanism by which this occurs is substantially identical to that already discussed in detail in relation to end structure 180 in Figure 13.

End structure 200 has been found to be particularly useful in directing laser energy onto tissue located to the side of a laser probe as, for example, on the wall of a body passageway. In contrast to the effect obtained by the inventive embodiments illustrated in Figures 8, 9, and 10, however, end structure 200 does not focus that laser energy into a narrow beam for the purpose of incising the tissue, but rather applies laser energy to that tissue in a large area contacted by the laser tip. The tip is thus ideally suited to vaporizing large volumes of tissue. Desirable hemostasis effects also accrue when end structure 200 is utilized.

Figures 17A through 17E illustrate the manner in which both end structure 180 and end structure 200 can be fabricated from an optical fiber 12. Initially,

reinforcing jacket 42 and hard cladding 40 are removed from a section of fiber core 38 immediately adjacent to end 70 thereof. The outer surface of fiber core 38 is thereafter cleaned, resulting in the structure illustrated in Figure 17A. The steps of the procedure to this point parallel those discussed already in relation to Figures 7A-7C.

Thereafter, end 70 of fiber core 38 is oriented downwardly in a generally vertical direction at an inclination angle C to a vertical axis V-V. With fiber core 38 rotating about the longitudinal axis Y_5-Y_5, as shown by arrow R, a first portion 220 adjacent to end 70 is heated by the application of heat H thereto. This can occur in any of the manners of heat application discussed previously in relation to the application of heat H as, for example, in relation to Figure 7D. Heat H is applied to first portion 220 for sufficient time to permit first portion 220 to assume a molten state. Thereafter, the surface tension on the molten form of first portion 220 causes first portion 220 to assume the bulbous shape 222 shown in Figure 17C as having smoothly flaring sides 224 and a diameter E_3 that is greater than the diameter D_4 of fiber core 38. Bulbous shape 222 is then cooled resulting in an axially aligned orbicular end structure 226 equivalent to end structure 180 shown in Figure 13.

Further processing is required in order to produce an off-axis orbicular end structure, such as end structure 200

shown in Figure 16. As illustrated in Figure 17D, heat H is applied to a second portion 228 of the length of fiber core 38 that is located intermediate and adjacent to end structure 226 and a third portion 230 of fiber core 38. Simultaneously, a force F_5 directed normal to longitudinal axis Y_5-Y_5 of fiber core 38 is applied to end structure 226. Much in the manner already discussed in relation to Figure 12C, the heat H applied to second portion 228 renders second portion 228 molten, so that force F_5 is able to bend second portion 228 out of alignment with longitudinal axis Y_5-Y_5 of fiber core 38 into the bent position shown in Figure 17E. Cooling produces a device corresponding to end structure 200 shown in Figure 16.

The end structure produced in this manner is both integral with fiber core 38 and has surfaces free of scratches and polishing abrasions. It is, therefore, capable of transmitting laser energy delivered from fiber core 38 in a highly efficient manner, without generating unwanted heat. In the case of the orbicular or spherical end structure created in this manner, the vaporization of large volumes of tissue by direct contact therewith is particularly facilitated, and the control of blood flow from severed tissues is greatly enhanced. Axially aligned and axially off-set configurations of the orbicular tip have specific special applications.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An optical waveguide for use in a medical procedure for the transmission of laser energy from a medical laser to tissue to be treated according to the medical procedure, said waveguide comprising:

(a) a fiber core of optically transmissive material having an input end for receiving the laser energy and an output end remote therefrom for delivering the laser energy to the tissue; and

(b) tip means formed of said optically transmissive material integrally with said fiber core for directing laser energy from said output and of said fiber core and for delivering said laser energy with high transmission efficiency to selected portions of the tissue.

2. An optical waveguide as recited in Claim 1, wherein said tip means comprises an end structure on said output end of said fiber core, said end structure having surfaces free of polishing abrasions.

3. An optical waveguide as recited in Claim 2, wherein said end structure is formed from a molten portion of said fiber core.

4. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for internally star-reflecting a first portion of the laser energy delivered from said output end of said fiber core in an avalanche mode of transmission and for directing said multi-directional laser energy through the boundary of said region of multi-directional energy at such portions of said boundary as contact the tissue, said first portion of the laser energy corresponding to high order rays of laser energy delivered from said output and of said fiber core.

5. An optical waveguide as recited in Claim 4, wherein said region of multi-directional laser energy is orbicular.

6. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting in a carrier mode of transmission focuses a second portion of the laser energy delivered from said output end of said fiber core through a fast focal point aligned with the longitudinal axis of the fiber core at the output end thereof, said second portion of the laser energy corresponding to low order rays of laser energy delivered from said output end of said fiber core.

7. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting comprises a positive lens.

8. An optical waveguide as recited in Claim 4, wherein said means for internally star-reflecting comprises an end structure on said output end of said fiber core, having surfaces defining the boundary of said region of multi-directional laser energy, said surfaces of said end structure being free of polishing abrasions.

9. An optical waveguide as recited in either of Claims 8 or 2, wherein said end structure comprises:

(a) a lens portion disposed at said output end of said fiber core concentrically with the longitudinal axis thereof; and

(b) a transition portion smoothly connecting the surface of said lens portion to the sides of said fiber core.

10. An optical waveguide as recited in either of Claims 8 or 2, wherein said end structure comprises:

(a) a generally cylindrical bend portion having a proximal end radially coextensive with said output end of said fiber core and a distal end opposite therefrom, the longitudinal axis of said bend portion at said distal end thereof diverting from the longitudinal axis of said output end of said fiber core at a predetermined bend angle;

(b) a lens portion disposed at said distal end of said bend portion concentrically with the longitudinal axis thereof; and

(c) a transition portion smoothly connecting the surface of said lens portion to the sides of said distal end of said bend portion.

11. An optical waveguide as recited in either of Claims 9 or 10, wherein said lens portion is orbicular.

12. An optical waveguide as recited in either of Claims 9 or 10, wherein the diameter of said lens portion is greater than the diameter said distal end of said bend portion.

13. An optical waveguide as recited in Claim 12, wherein the diameter of said lens portion is in the range of about 0.3 millimeters to about 5.0 millimeters.

14. An optical waveguide as recited in Claim 13, wherein the diameter of said lens portion is in the range of about 0.6 millimeters to about 3.0 millimeters.

15. An optical waveguide as recited in Claim 14, wherein the diameter of said lens portion is in the range of about 0.8 millimeters to about 2.5 millimeters.

16. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for focusing a second portion of the laser energy delivered from said output end of said laser core in a carrier mode of transmission through a fast focal point aligned with the longitudinal axis of the fiber core at said output end thereof, said second portion of the laser energy corresponding to low order rays of laser energy from said output end of said fiber core, and said means for focusing being formed of said optically transmissive material integrally with said fiber core at said output end thereof.

17. An optical waveguide as recited in Claim 16, wherein said means for focussing comprises a positive lens.

18. An optical waveguide as recited in Claim 17, wherein said means for focusing comprises an end structure on said output end of said fiber core, having surfaces free of polishing abrasions.

19. An optical waveguide as recited in Claim 18, wherein a first portion of the laser energy from said output end of said fiber core is transmitted in an avalanche mode of transmission through the surface of said lens portion at such portions thereof as contact the tissue, said first portion of the laser energy corresponding to high order rays of laser energy from said output end of said fiber core.

20. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for narrowly focusing the laser energy from said output end of said fiber core onto portions of the tissue offset laterally from the longitudinal axis of said fiber core at said output end thereof.

21. An optical waveguide as recited in Claim 20, wherein said means for narrowly focusing comprises an end structure on said output end of said fiber core having side surfaces free of polishing abrasions, thereby minimizing the diffusion of laser energy through said side surfaces of said end structure.

22. An optical waveguide as recited in either of Claims 2 or 21, wherein said end structure comprises:

(a) a generally cylindrical bend portion having a proximal end radially coextensive with said output end of said fiber core and a distal end opposite therefrom, the longitudinal axis of said bend portion at said distal end thereof diverting from the longitudinal axis of said output end of said fiber core at a predetermined bend angle; and

(b) a tip formed on said distal end of said bend portion.

23. An optical waveguide as recited in either of Claims 10 or 22, wherein said predetermined bend angle at which the longitudinal axis of said bend portion at said distal end thereof diverts from the longitudinal axis of said output end of said fiber core ranges upwardly to approximately 90°.

24. An optical waveguide as recited in Claim 23, wherein the measure of said predetermined bend angle is in the range of about 15° to about 60°.

25. An optical waveguide as recited in Claim 24, wherein the measure of said predetermined bend angle is in the range of about 30° to about 45°.

26. An optical waveguide as recited in either of Claims 10 or 22, wherein the length of said bend portion is in the range of about 0.5 millimeters to about 1.5 millimeters.

27. An optical waveguide as recited in Claim 22, wherein said sides of said tip taper smoothly from a first end adjacent said proximal end of said bend portion to a terminus comprising a flat surface at a second end remote therefrom.

28. An optical waveguide as recited in Claim 22, wherein said terminus of said tip is disposed normal to the plane of said bend portion and parallel to the longitudinal axis of said fiber core at said output end thereof.

29. An optical waveguide as recited in Claim 22, wherein said terminus of said tip is normal to the longitudinal axis of said tip.

30. An optical waveguide as recited in Claim 22, wherein said bend portion is formed from a molten portion of said fiber core by twisting out of longitudinal alignment portions of said fiber core on opposite sides of said a molten portion.

31. An optical waveguide as recited in Claim 22, wherein said tip is formed by drawing a molten portion of said fiber core located on the side of said bend portion opposite from said output end of said fiber core away from said bend portion in a direction aligned with the longitudinal axis of said bend portion at said distal end thereof.

32. An optical waveguide as recited in Claim 1, wherein said tip means comprises means for narrowly focusing the laser energy from said output end of said fiber core onto portions of the tissue aligned with the longitudinal axis of said fiber core at said output end thereof.

33. An optical waveguide as recited in Claim 32, wherein said means for narrowly focusing comprises an end structure in the form of a tip on said output end of said fiber core having side surfaces free of polishing abrasions, thereby minimizing the diffusion of laser energy through said side surfaces of said tip.

34. An optical waveguide as recited in Claim 33, wherein said sides of said tip taper smoothly from a first end adjacent said fiber core to a terminus at a second end remote from said fiber.

35. An optical waveguide as recited in Claim 34, wherein said terminus of said tip comprises a flat surface disposed normal to the longitudinal axis of said fiber core.

36. An optical waveguide as recited in either of Claims 29 or 32, wherein said tip is frustoconical.

37. An optical waveguide as recited in Claim 36, wherein the length of said tip is in the range of about 1.5 millimeters to about 7.0 millimeters.

38. An optical waveguide as recited in Claim 37, wherein the length of said tip is in the range of about 1.5 millimeters to about 2.5 millimeters.

39. An optical waveguide as recited in either of Claims 27 or 33, wherein the diameter of said terminus of said tip is in the range of about 75 microns to about 300 microns.

40. An optical waveguide as recited in Claim 39, wherein the diameter of said terminus of said tip is in the range of about 75 microns to about 125 microns.

41. An optical waveguide as recited in either of Claims 27 or 33, wherein the apex angle formed by projecting said sides of said tip to an intersection beyond the terminus thereof is in the range of about 4 degrees to about 45 degrees.

42. An optical waveguide as recited in Claim 41, wherein the apex angle formed from projecting said sides of said tip to an intersection beyond the terminus thereof is in the range of about 9 degrees to about 20 degrees.

43. An optical waveguide as recited in Claim 33, wherein said tip is rotationally symmetric.

44. An optical waveguide as recited in Claim 43, wherein said tip is formed by drawing a molten portion of said output end of said fiber core away from said fiber core in a direction aligned with the longitudinal axis thereof.

45. An optical waveguide as recited in either of Claims 8, 21, or 33, wherein said end structure is formed from a molten portion of said fiber core.

46. An optical waveguide as recited in Claim 1, wherein said optically transmissive material has an index of refraction similar to that of the tissue.

47. An optical waveguide as recited in Claim 46, wherein said optically transmissive material comprises quartz.

48. An optical waveguide as recited in Claim 45, wherein said optically transmissive material comprises silica.

49. An optical waveguide as recited in Claim 46, wherein said optically transmissive material comprises a thermoplastic material.

50. An optical waveguide as recited in either one of Claims 8, 21, or 33, further comprising a flexible jacket surrounding said fiber core, and wherein said end structure is free of said flexible jacket.

51. An optical waveguide as recited in Claim 51, further comprising a cladding about said flexible jacket for stiffening said fiber core.

52. An optical waveguide as recited in Claim 51, further comprising a handle fixed to and surrounding said cladding in the vicinity of said tip.

53. An optical waveguide as recited in Claim 1, wherein said fiber core is comprised of a first optically transmissive solid material having an index of refraction similar to that of the tissue; and wherein said waveguide further comprises a sheath surrounding said fiber core, said sheath being comprised of a second optical transmissive solid material having an index of refraction substantially equal to said first index of refraction.

54. An end structure for an optical laser fiber core, said end structure being integrally formed with said fiber core so as to be radially coextensive at a first end thereof with the end of said fiber core and to have sides flaring smoothly outward from said first end to a terminus at a second end remote from said fiber core.

55. An end structure as recited in Claim 54, wherein the surface of said sides of said end structure are free from polishing abrasions, thereby minimizing the diffusion of laser energy through said side surfaces of said end structure.

56. An end structure as recited in Claim 55, wherein said end structure comprises a tip for said fiber core taking form of a generally hemispherical shape.

57. An end structure as recited in Claim 56, wherein said terminus of said tip comprises the planar surface of said generally hemispherical shape.

58. An end structure as recited in Claim 54, wherein said tip comprises a bulbous shape having a maximum diameter taken normal to the longitudinal axis of said fiber core that is greater than the diameter of said fiber core, the sides of said bulbous shape smoothly merging into the sides of said fiber core, and said bulbous shape terminating at the end thereof remote from said fiber core in a flat surface disposed normal to the longitudinal axis of said fiber core.

59. An end structure as recited in Claim 58, wherein said flat surface of said bulbous shape comprises said terminus of said tip.

60. An end structure as recited in Claim 54, wherein said tip is located at the input of said fiber core.

61. An end structure as recited in Claim 54, wherein said tip is located at the output end of said fiber core.

62. An end structure as recited in Claim 54, wherein the maximum diameter of said tip taken normal to the longitudinal axis of said fiber core is in the range of from about 600 microns to about 800 microns.

63. A method for making a tip for an optical waveguide for use with a medical laser in a predetermined medical procedure, said method comprising the steps:

(a) heating a first portion of the length of a fiber core of optically transmissive material to render said first portion molten, said first portion of said fiber core being located intermediate and adjacent to second and third portions of said fiber;

(b) drawing said third portion of said fiber core away from said heated first portion parallel to the longitudinal axis of said fiber thereby to produce from said heated first portion, at the end thereof adjacent said second portion of said fiber core, a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from said second portion;

(c) cooling said shape;

(d) scoring said shape at a scoring point located a preselected distance along said shape from said second portion of said fiber core; and

(e) breaking said shape at said scoring point to form from said shape integrally with said second portion of said fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through said fiber core to said second portion thereof.

64. A method for making a tip for the end of an optical fiber core, said method comprising the steps:

(a) orienting the end of the optical fiber core in a vertical direction;

(b) heating a first portion of the length of the fiber core adjacent the end thereof to render said first portion molten;

(c) maintaining the vertical orientation of said fiber core to permit said heated first portion thereof to assume a bulbous shape having smoothly flaring sides and a maximum diameter taken normal to the longitudinal axis of said fiber core that is greater than the diameter of said fiber;

(d) cooling said bulbous shape; and

(e) removing the end of said shape remote from the fiber core to produce thereat a flat surface disposed normal to the longitudinal axis of the fiber core.

65. A method for making an end structure for the output end of an optical waveguide useable with a medical laser in a predetermined medical procedure, said method comprising the steps:

(a) heating a first portion of the length of a fiber core of optically transmissive material to render said first portion molten, said first portion of said fiber core being located intermediate and adjacent to second and third portions of said fiber core;

(b) bending said first portion of said fiber core so that the longitudinal axis of said third portion is at a predetermined angle to the longitudinal axis of said second portion;

(c) cooling said second portion; and

(d) forming a tip from said first portion of said fiber core for narrowly focusing laser energy from the medical laser.

66. A method as recited in Claim 65, wherein said step of forming a tip from said third portion of said fiber core comprises the steps:

(a) heating a first section of the length of said third portion to render said first section molten, said first section being located intermediate and adjacent to second and third sections of said third portion, and said second section being adjacent to said first portion of said fiber core;

(b) drawing said third section of said third portion of said fiber core away from said heated first section parallel to the longitudinal axis of said first portion of said fiber core at the end thereof remote from said second portion of said fiber core, thereby to produce from said heated first section, at the end thereof adjacent said second section, a shape having smoothly tapering sides and a lateral cross-section decreasing with the distance from said second section; (c) cooling said shape;

(d) scoring said shape at a scoring point located a preselected distance along said shape from said second section; and

(e) breaking said shape at said scoring point to form from said shape integrally with said second section of said third portion of said fiber core a tip for narrowly focusing laser energy transmitted from the medical laser through said fiber core to said third portion thereof.

67. A method as recited in either of Claims 63, 64 or 65, further comprising the step of polishing said tip to produce at the end thereof a terminus comprising a flat surface.

68. A method as recited in either of Claims 63, 64 or 65, further comprising the step of polishing said tip to remove stress cracks at said scoring point.

69. A method as recited in either of Claims 63, 64 or 65, further comprising the step of removing the reinforcing jacket about said fiber core prior to said step of heating said first portion.

70. A method as recited in either of Claims 63, 64 or 65, further comprising the step of precleaning said fiber core to remove cladding therefrom prior to said step of heating said first portion.

71. A method as recited in Claim 70, wherein said step of precleaning comprises the step of exposing the outer surface of said fiber core to a flame.

72. A method as recited in Claim 70, wherein said step of precleaning comprises the steps of:

(a) washing said fiber core in an acetone bath; and

(b) drying said fiber core.

73. A method as recited in Claim 70, wherein said step of precleaning comprises the step of mechanically stripping cladding from said fiber core.

74. A method for making a tip for the end of an optical fiber core, said method comprising the steps of:

(a) orienting the end of the optical fiber core in a generally vertical direction;

(b) rotating said end of the optical fiber core about the longitudinal axis thereof;

(c) heating a first portion of the length of the fiber core adjacent the end thereof to render said first portion molten;

(d) permitting said heated first portion of said fiber core to assume a bulbous shape having smoothly flaring sides and a diameter that is greater than the diameter of said fiber; and

(e) cooling said bulbous shape.

75. A method as recited in Claim 74, wherein said step of orienting comprises the step of disposing the end of the optical fiber core in a downwardly oriented direction.

76. A method as recited in Claim 75, wherein said end of said optical fiber core is oriented at an inclination angle to the vertical in a range from about 10° to about 15°.

77. A method as recited in Claim 76, further comprising the steps:

(a) heating a second portion of the length of the fiber core to render said second portion molten, said second portion of said fiber core being located intermediate and adjacent to said first portion of said fiber core and a third portion of said fiber core;

(b) bending said second portion of said fiber core so that the longitudinal axis of said end thereof adjacent said first portion of said fiber core diverges at a predetermined angle from the longitudinal axis of said third portion of said fiber core; and

(c) cooling said second portion of said fiber core.

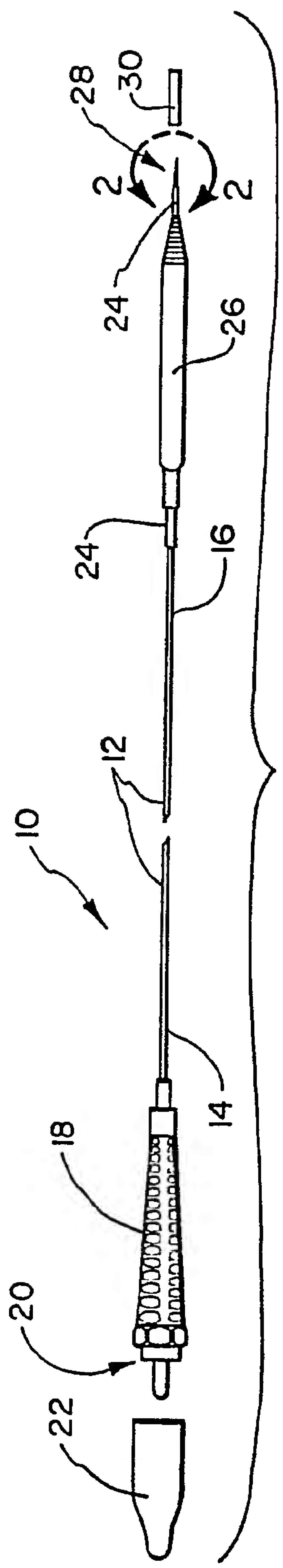


FIG. 1

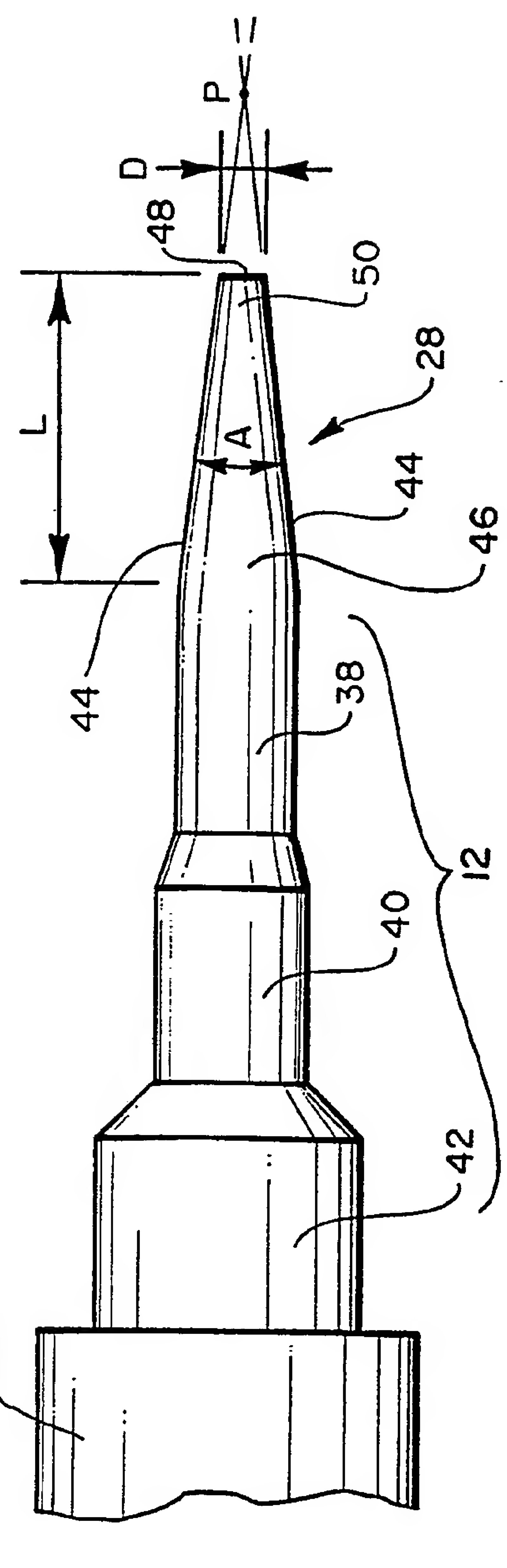


FIG. 2

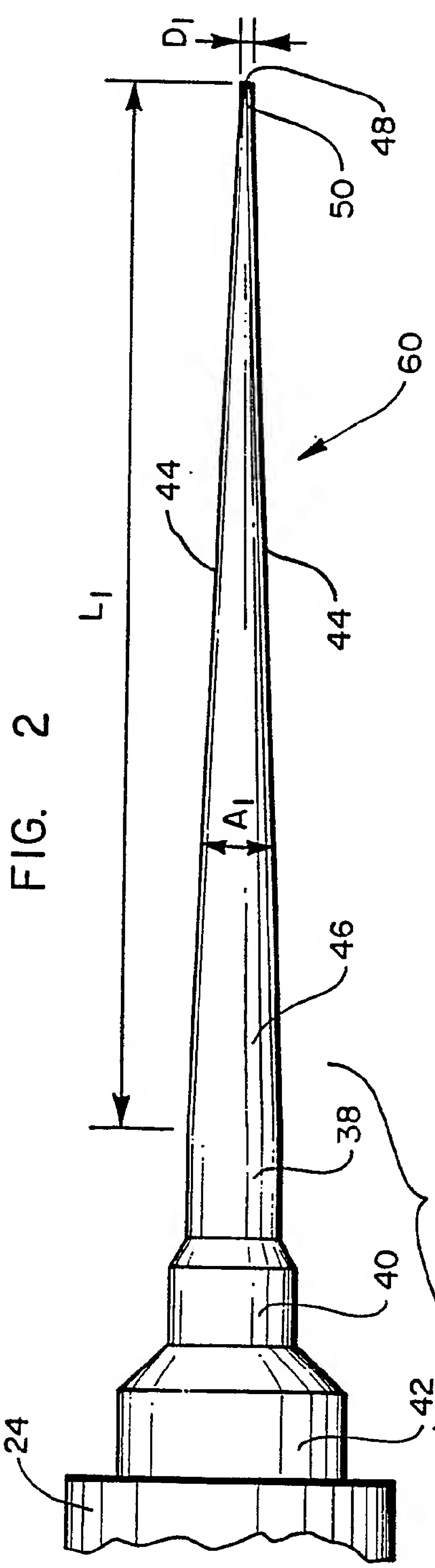


FIG. 3

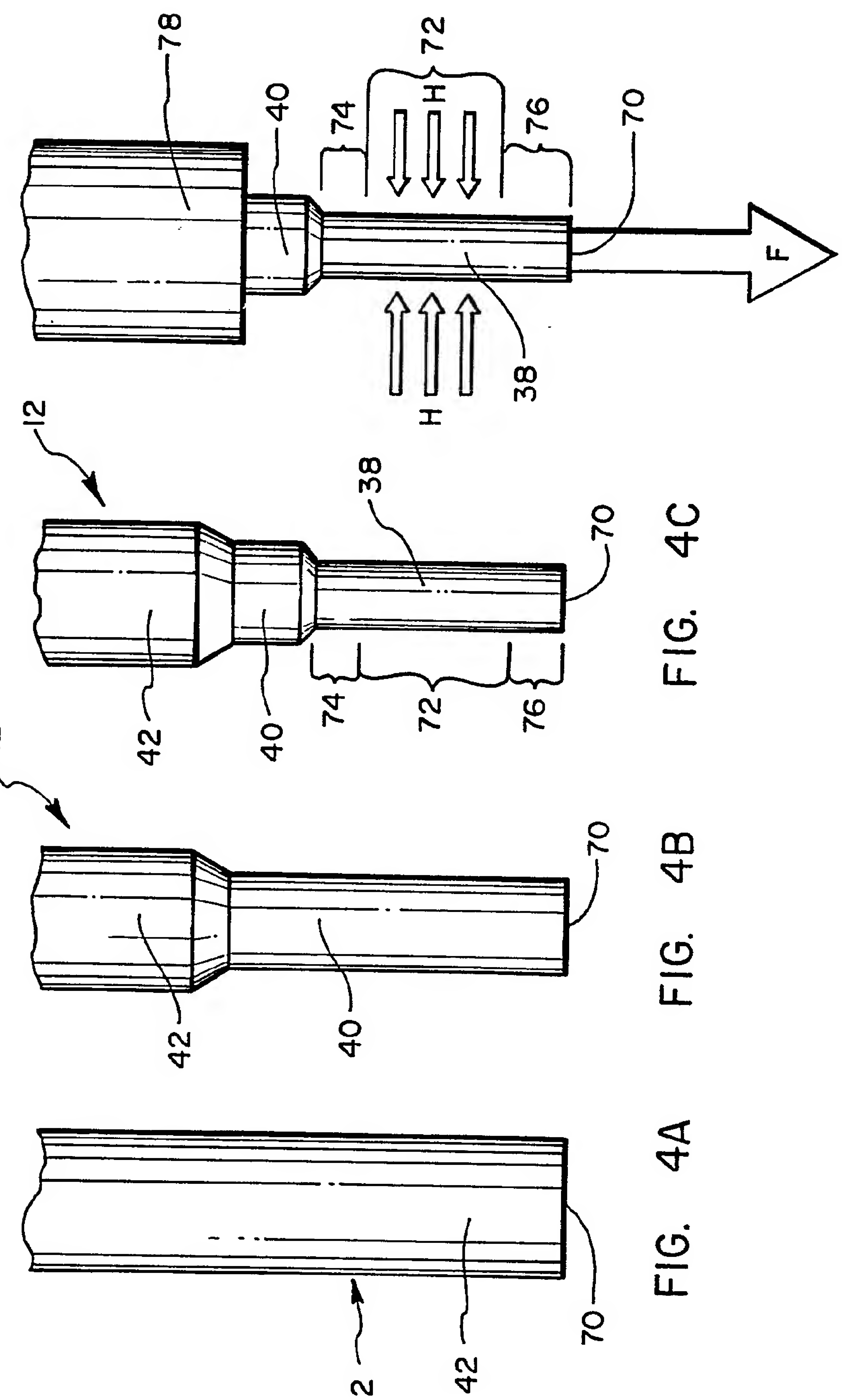


FIG. 4D

FIG. 4C

FIG. 4B

FIG. 4A

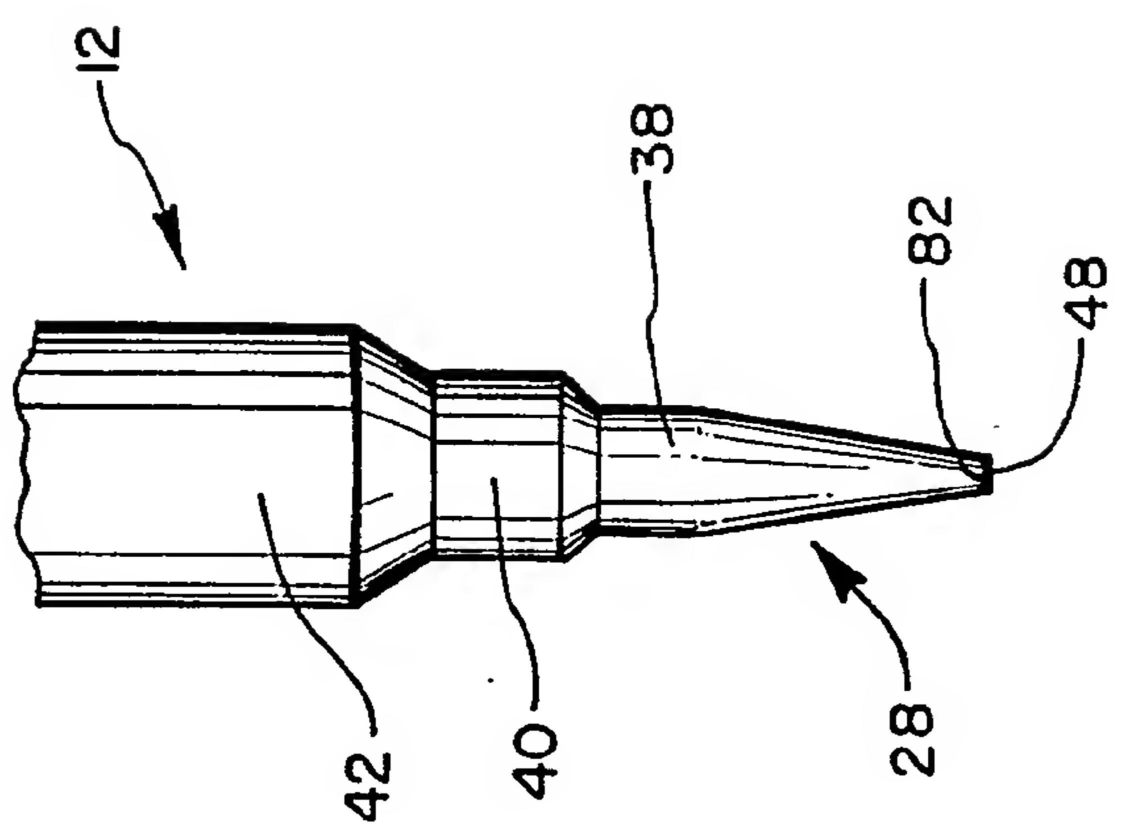


FIG. 4G

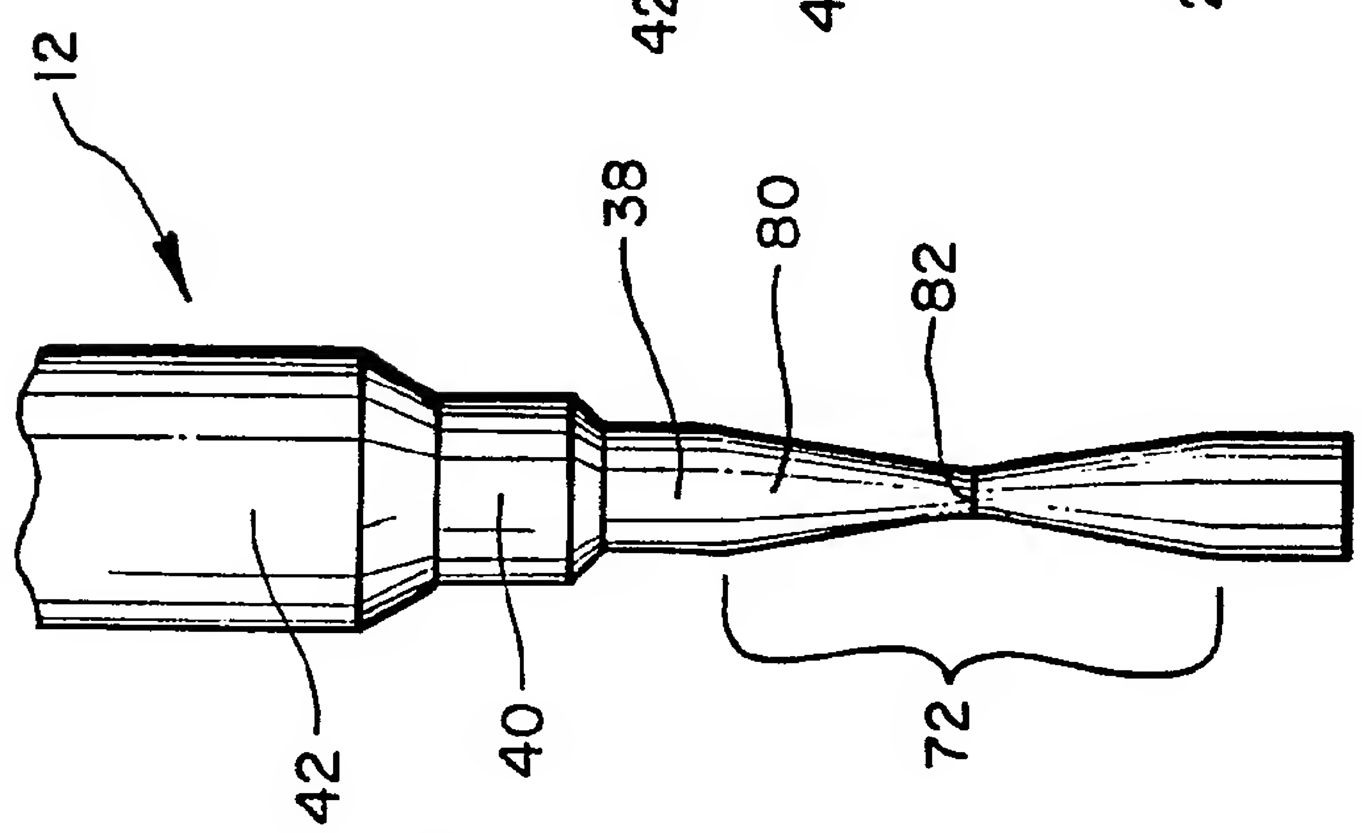


FIG. 4F

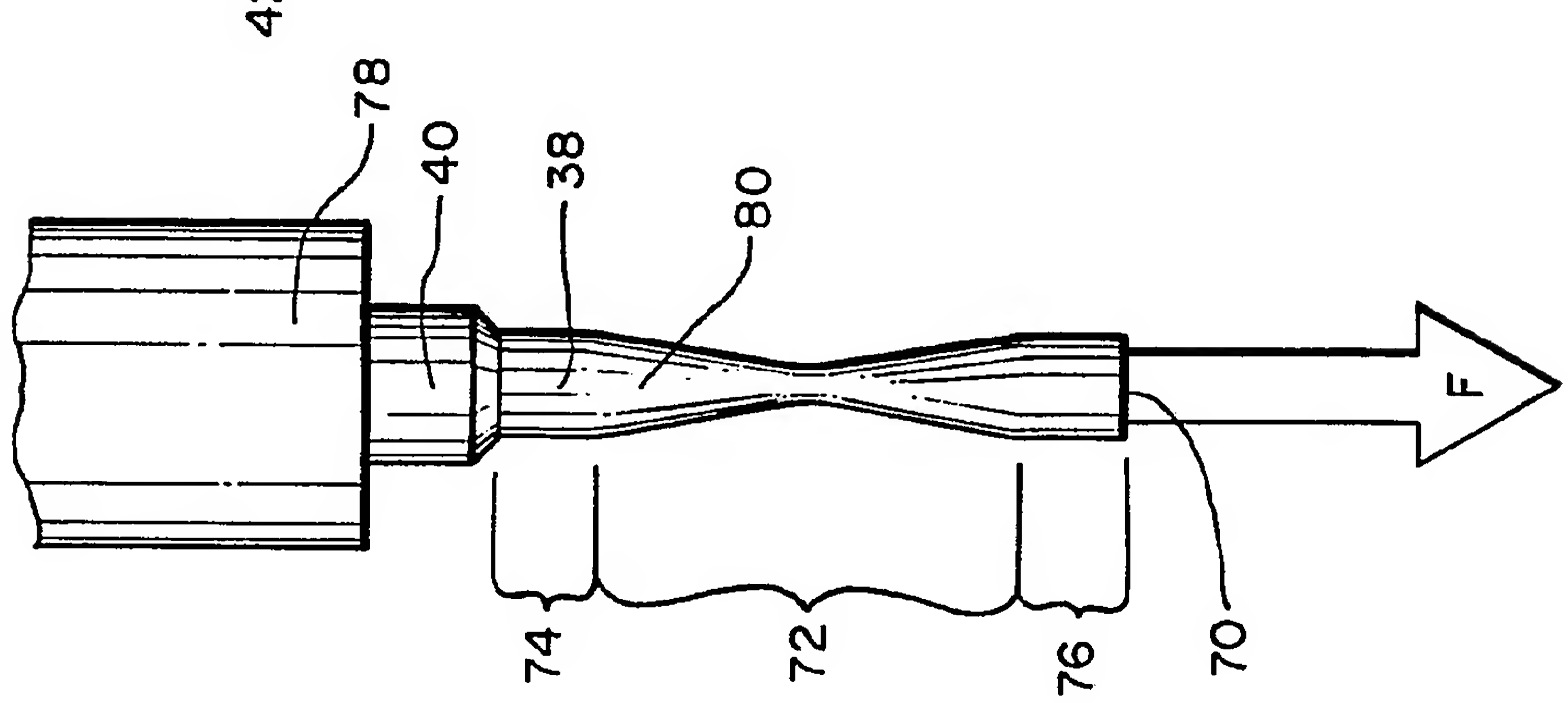


FIG. 4E

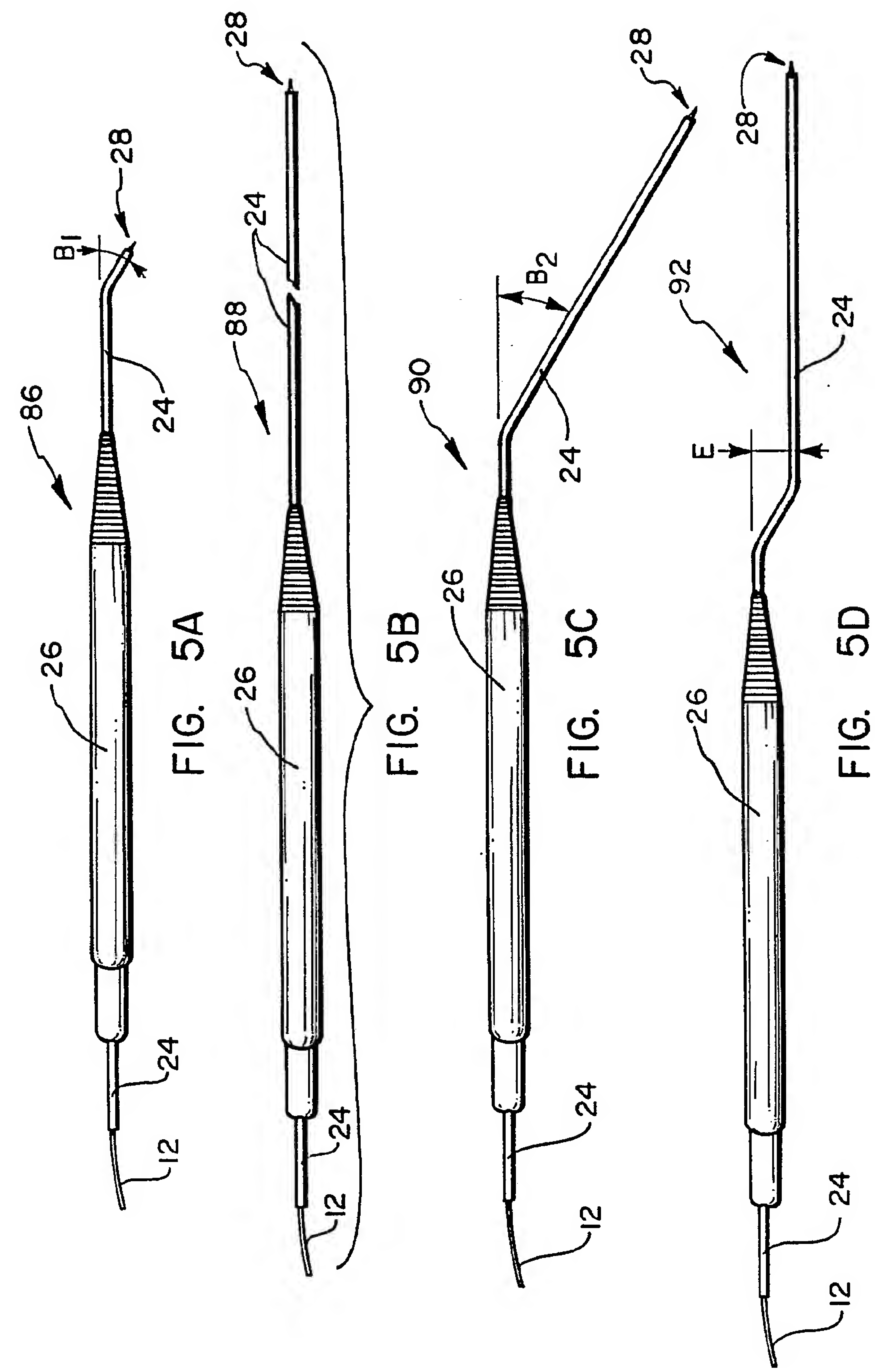


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

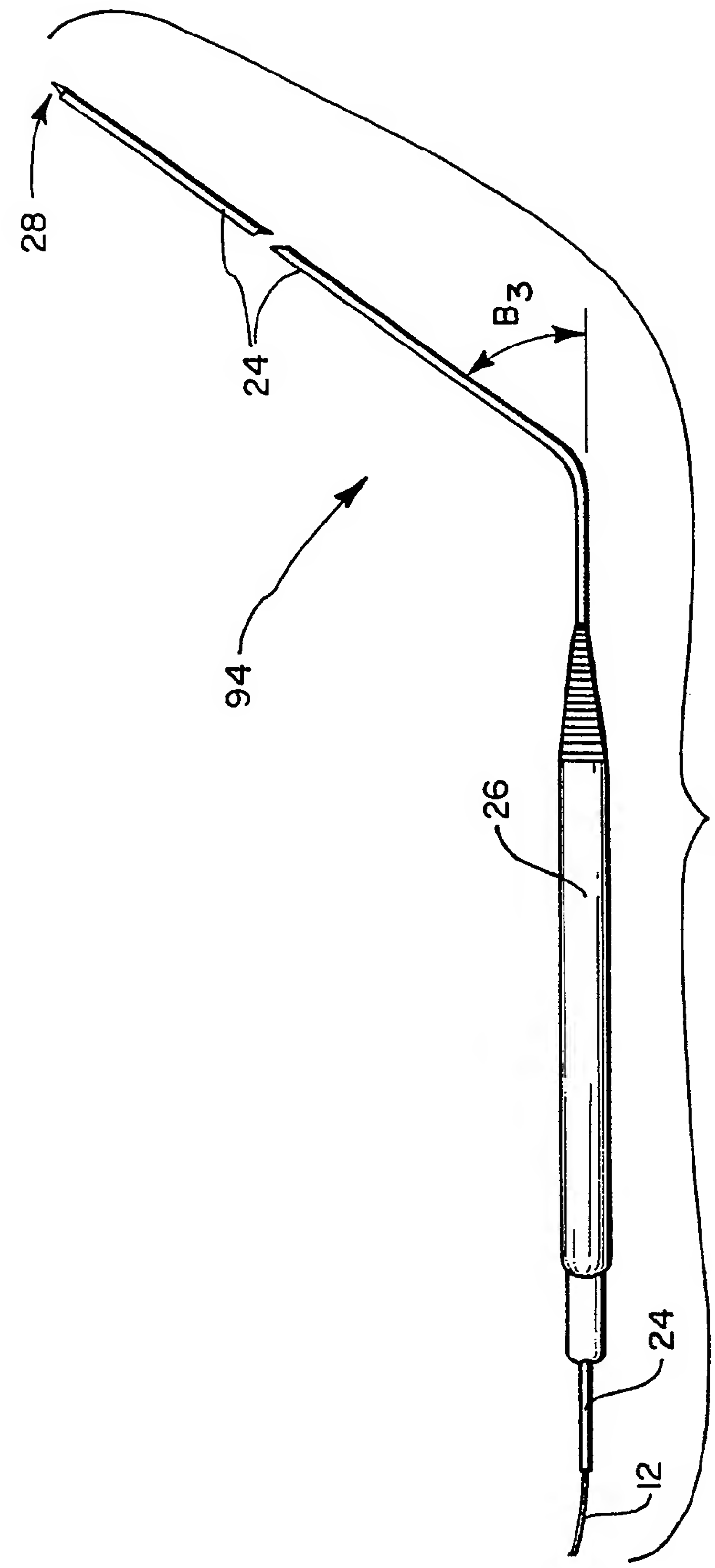


FIG. 5E

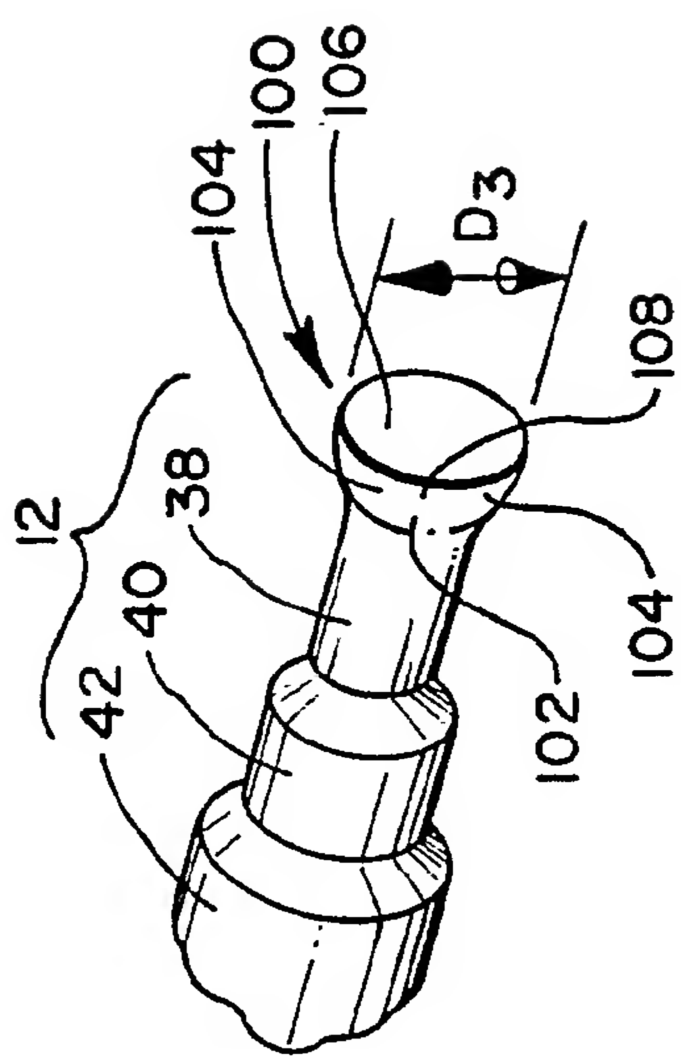


FIG. 6

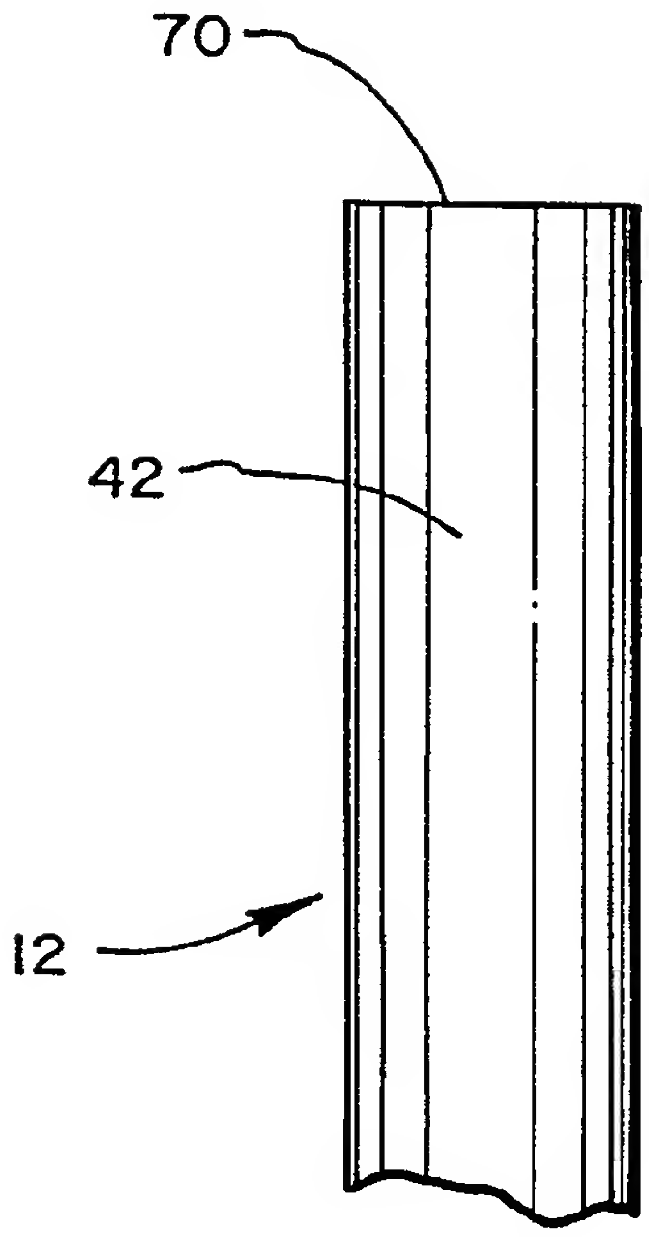


FIG. 7A

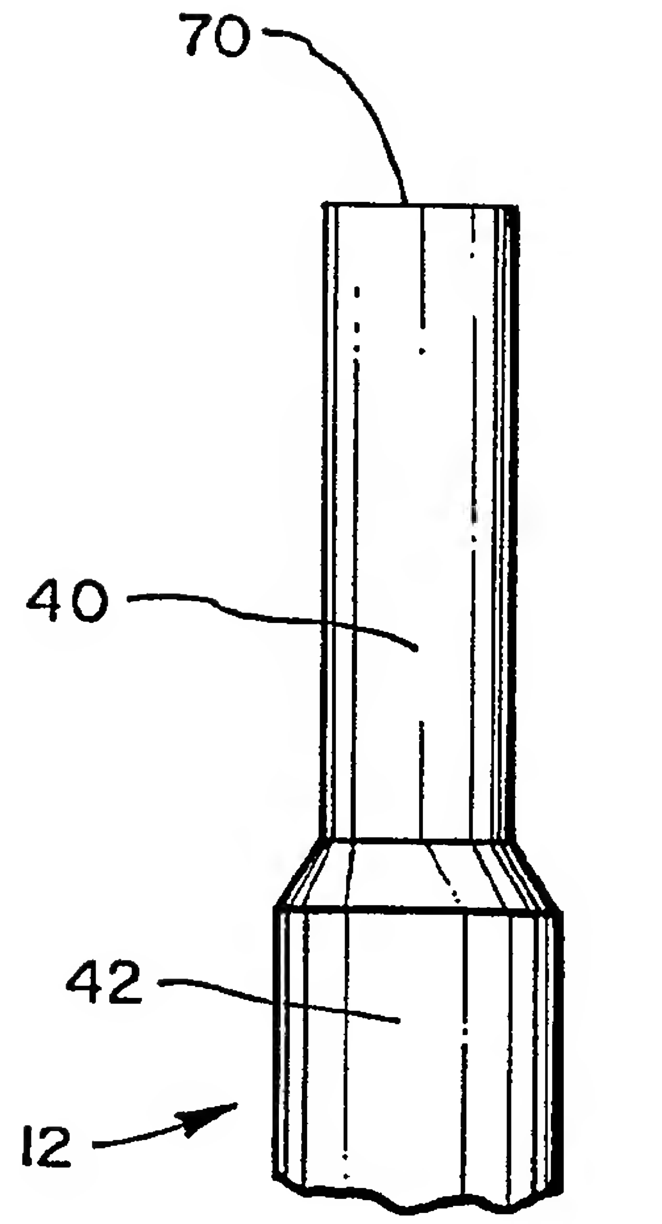


FIG. 7B

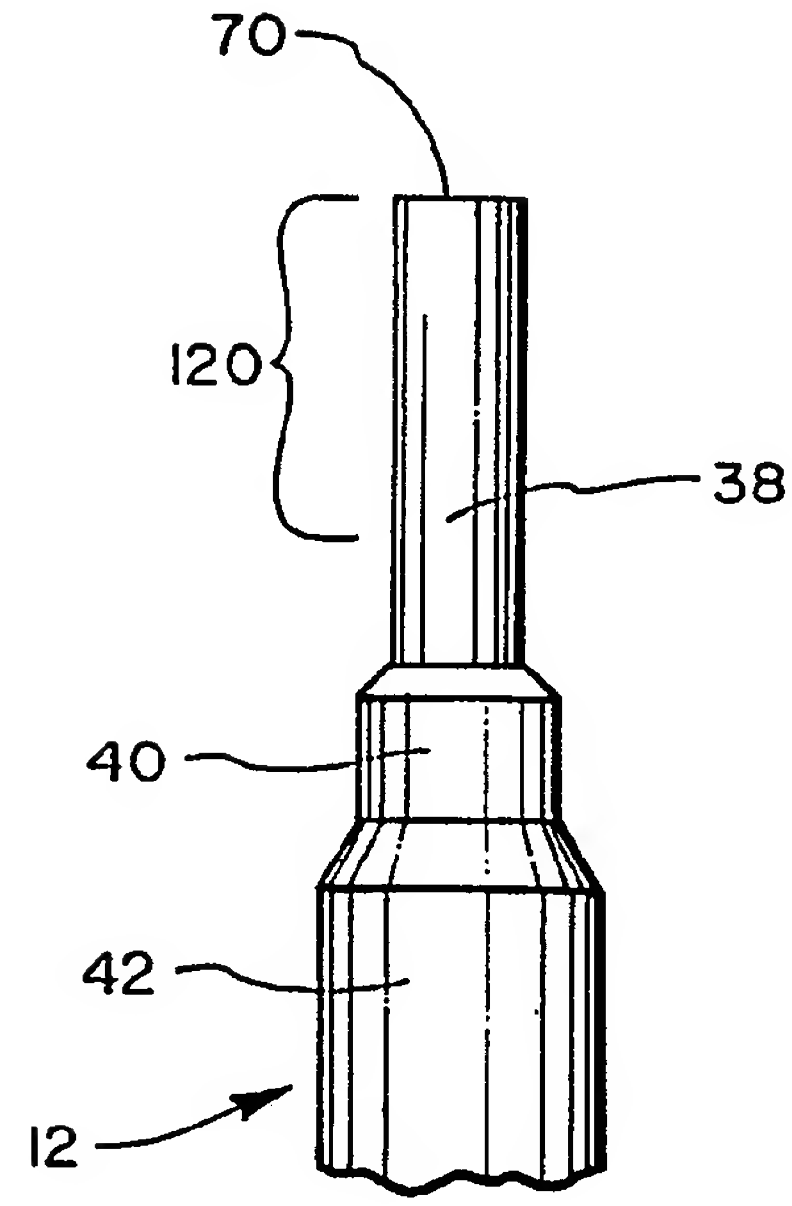


FIG. 7C

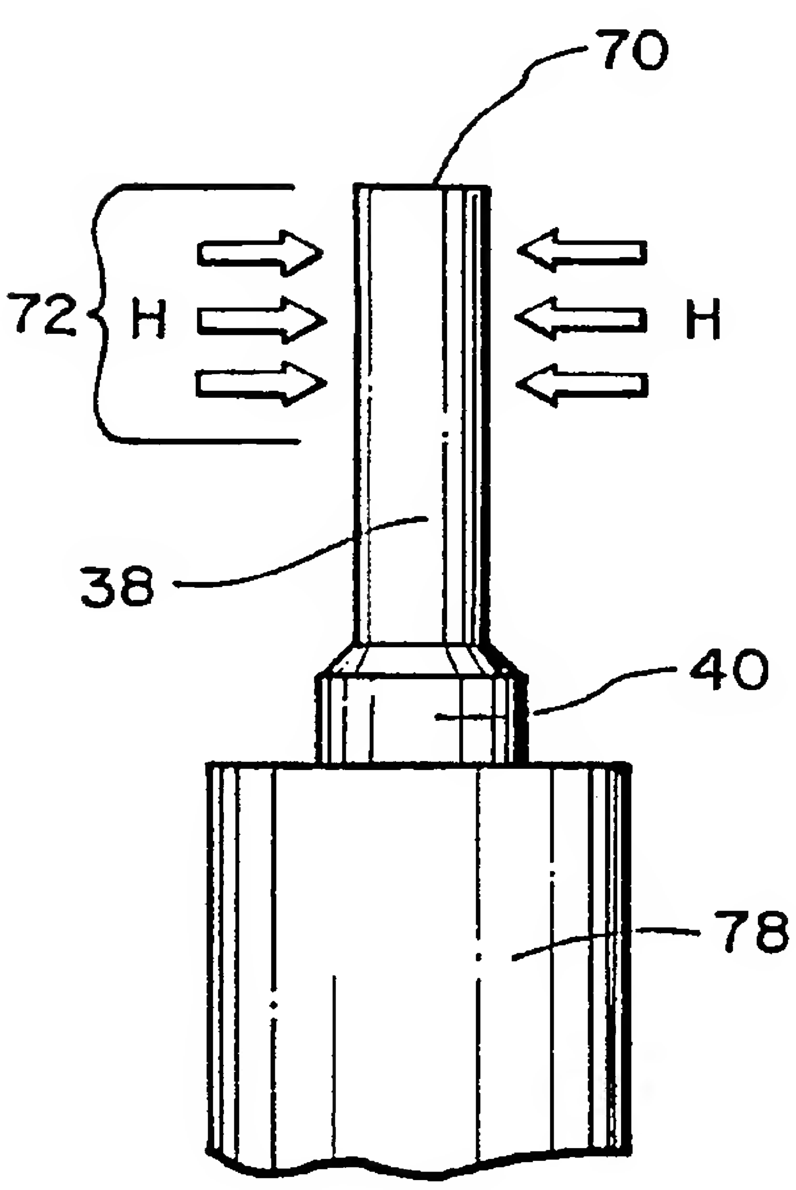


FIG. 7D

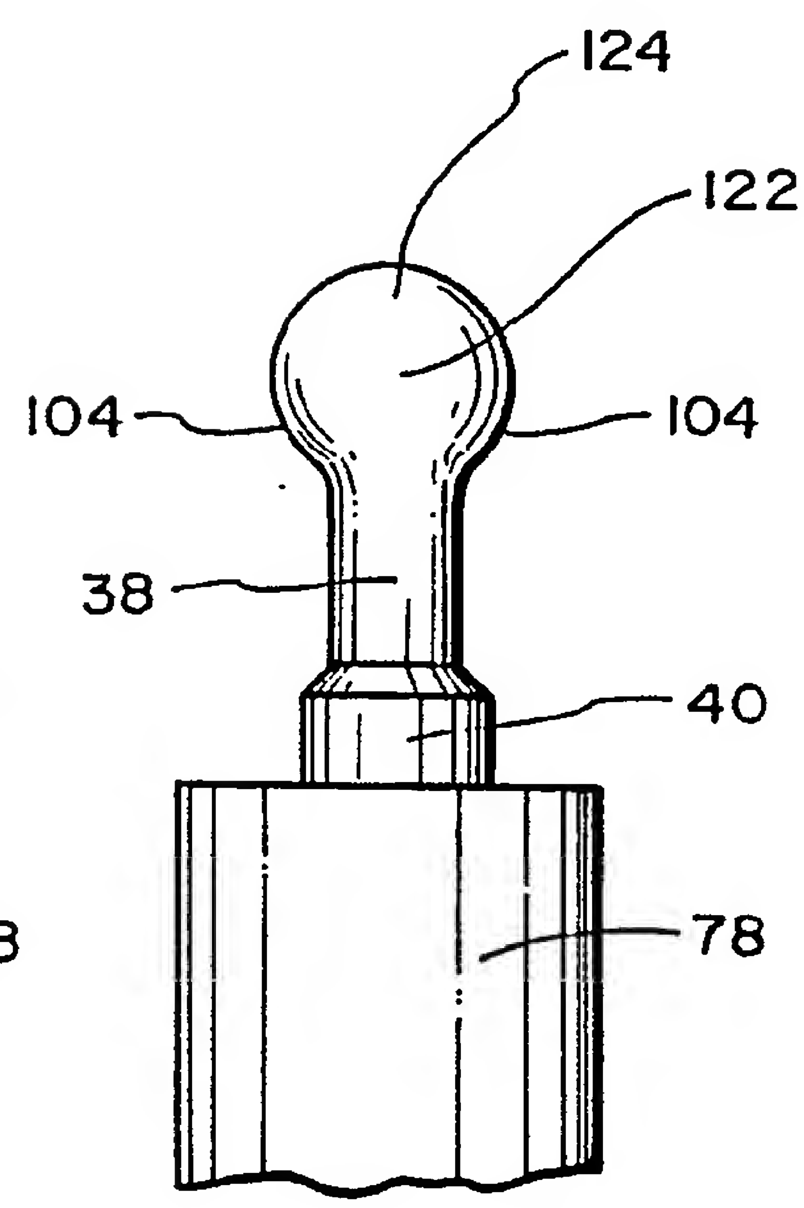


FIG. 7E

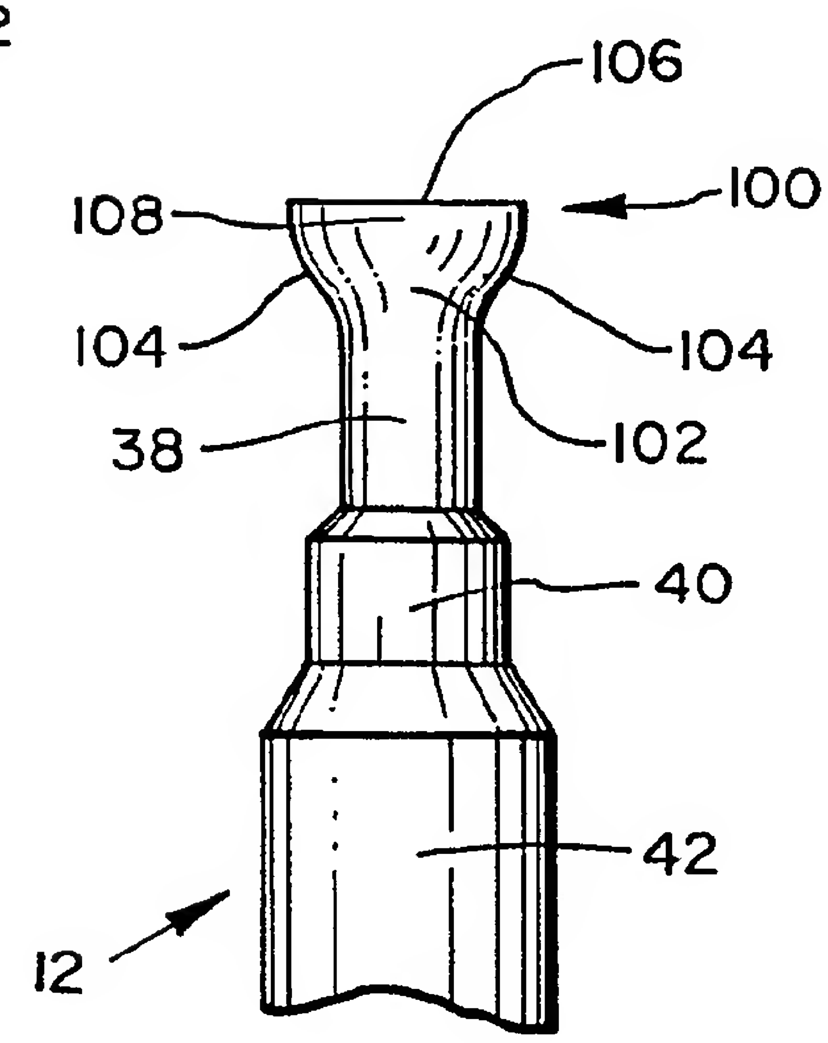


FIG. 7F

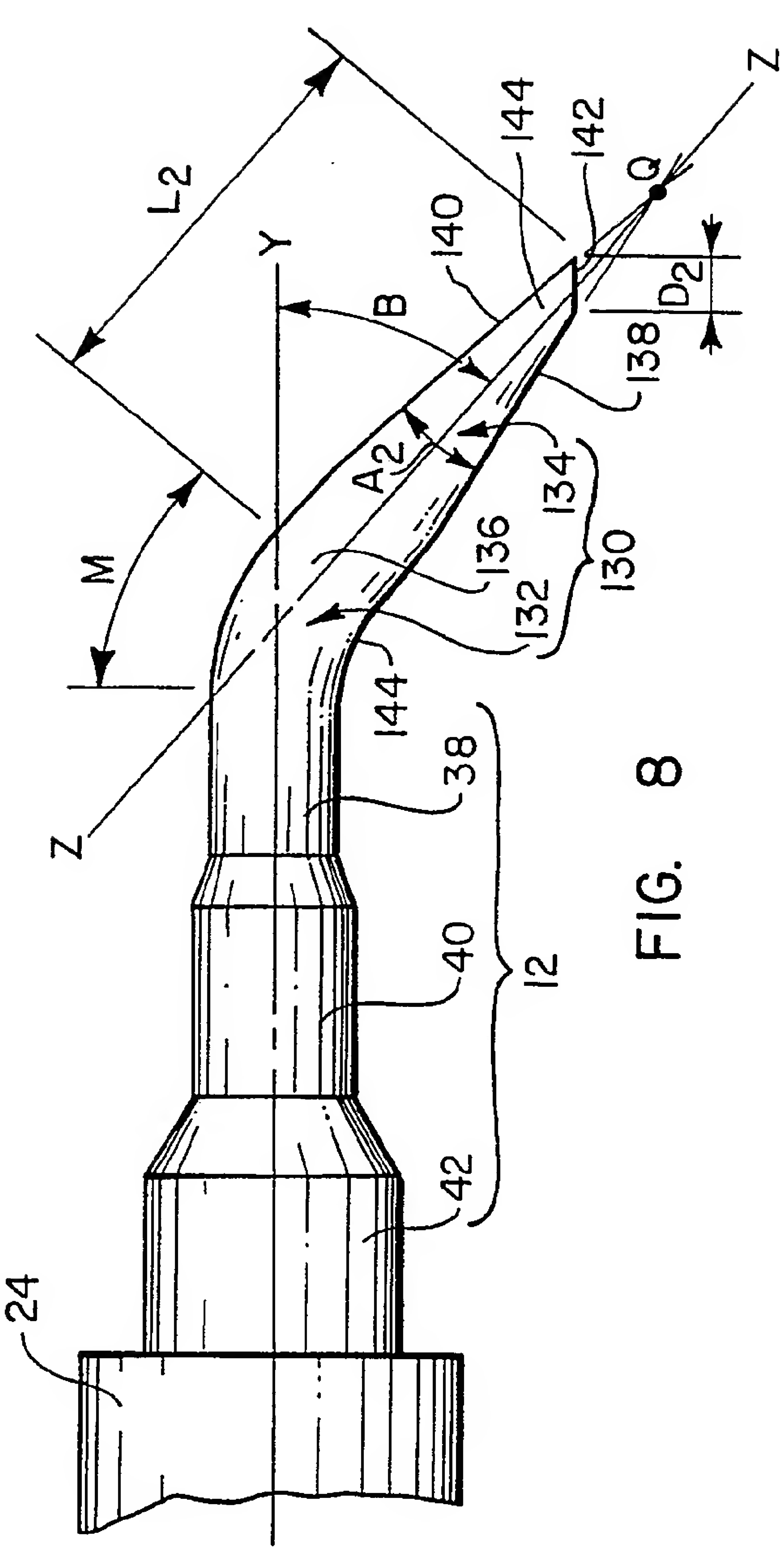

L2
Y
Z
Q
144
142
140
B
138
D2
A2
134
136
130
132
M
144
38
40
42
12
24
Y
Z

FIG. 8

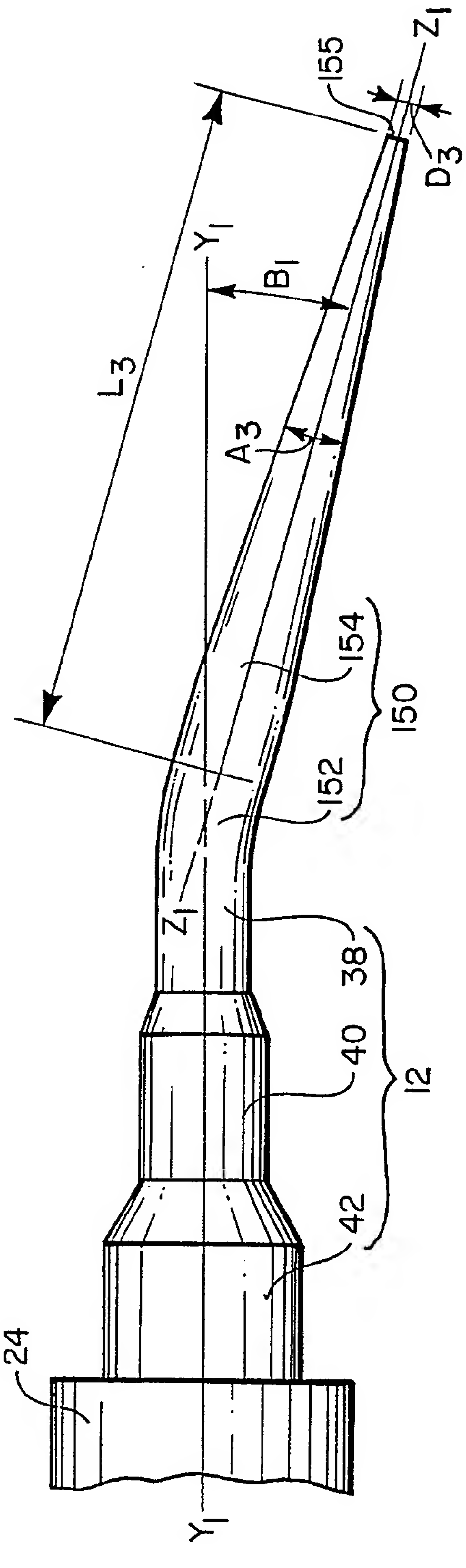
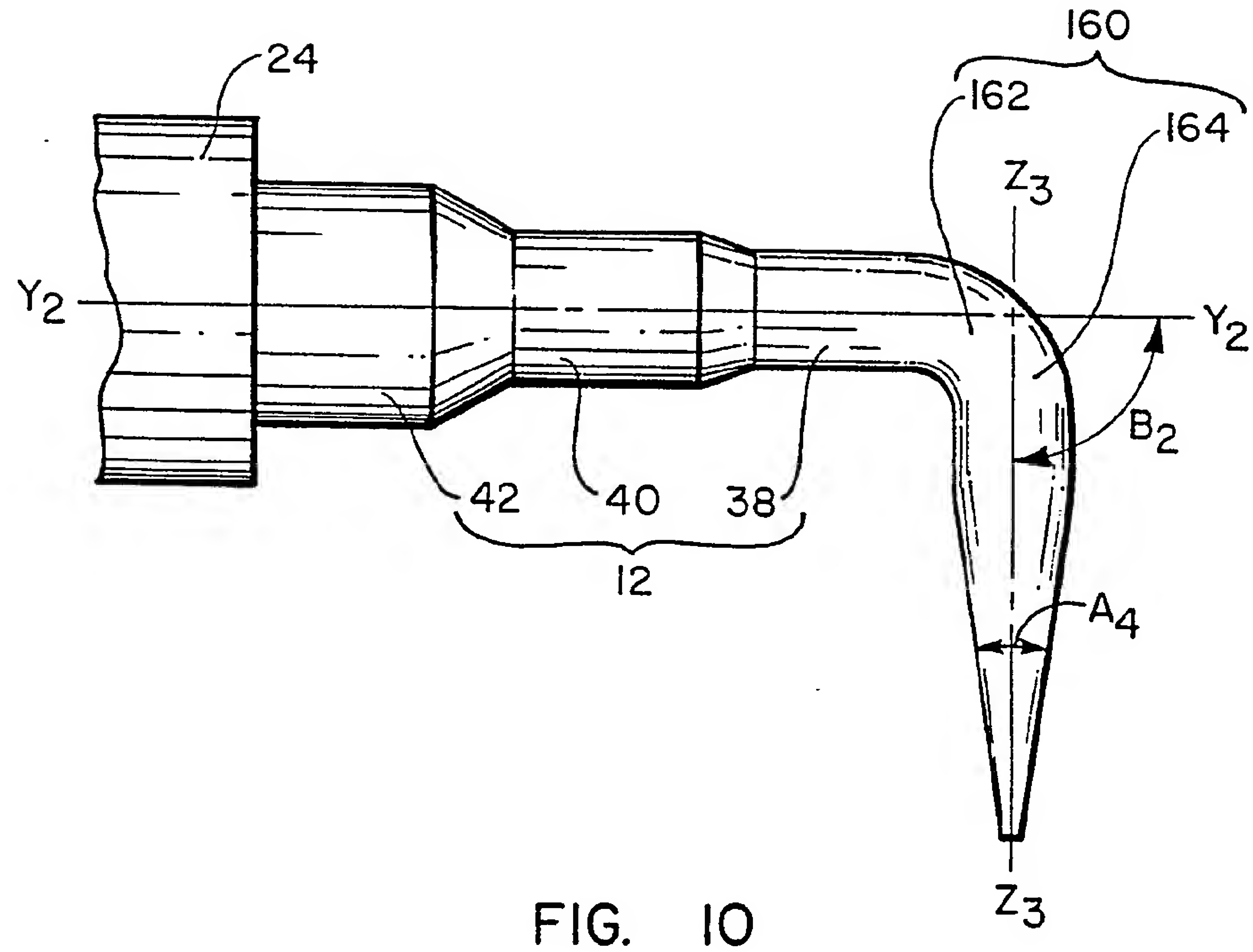
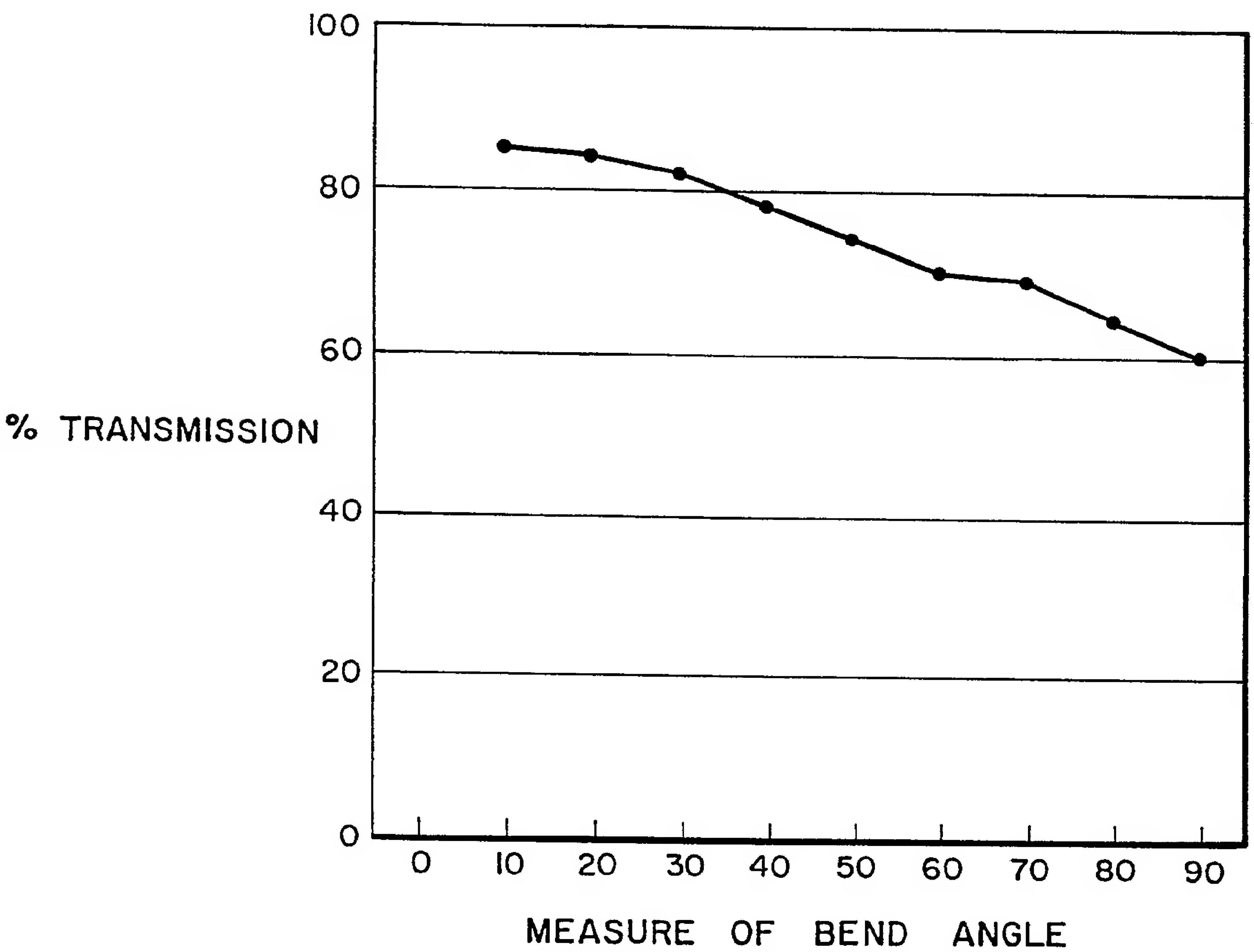

155
Z1
D3
Y1
B1
L3
A3
154
150
152
Z1
38
40
42
12
24
Y1

FIG. 9



160
24
162
164
Z_3
Y_2
Y_2
B_2
42
40
38
12
A_4
Z_3

FIG. 10



% TRANSMISSION
100
80
60
40
20
0
0
10
20
30
40
50
60
70
80
90
MEASURE OF BEND ANGLE

FIG. 11

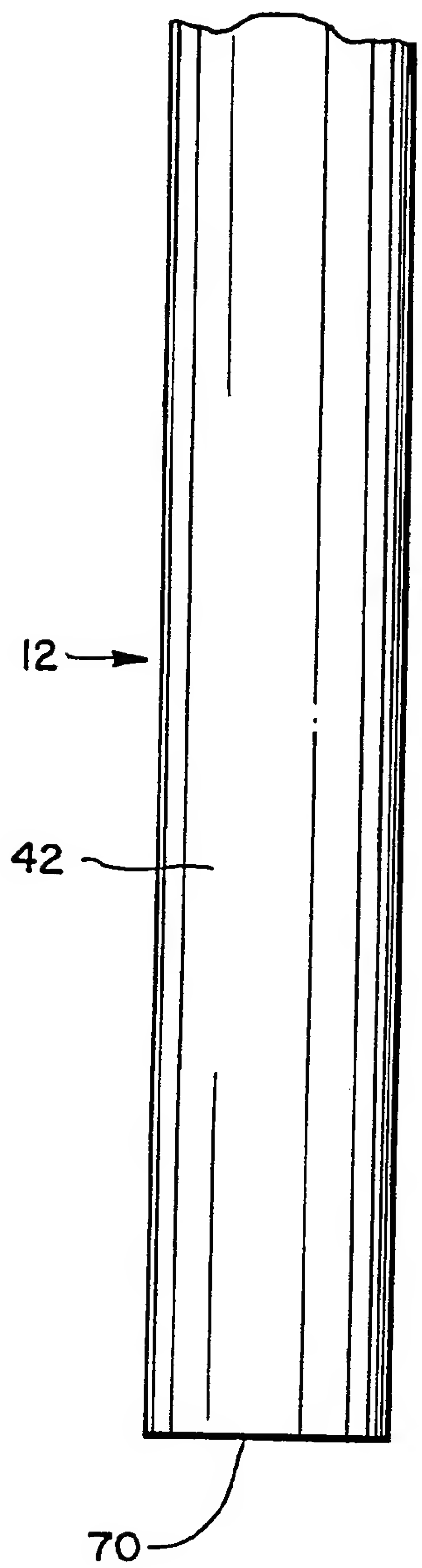


FIG. 12A

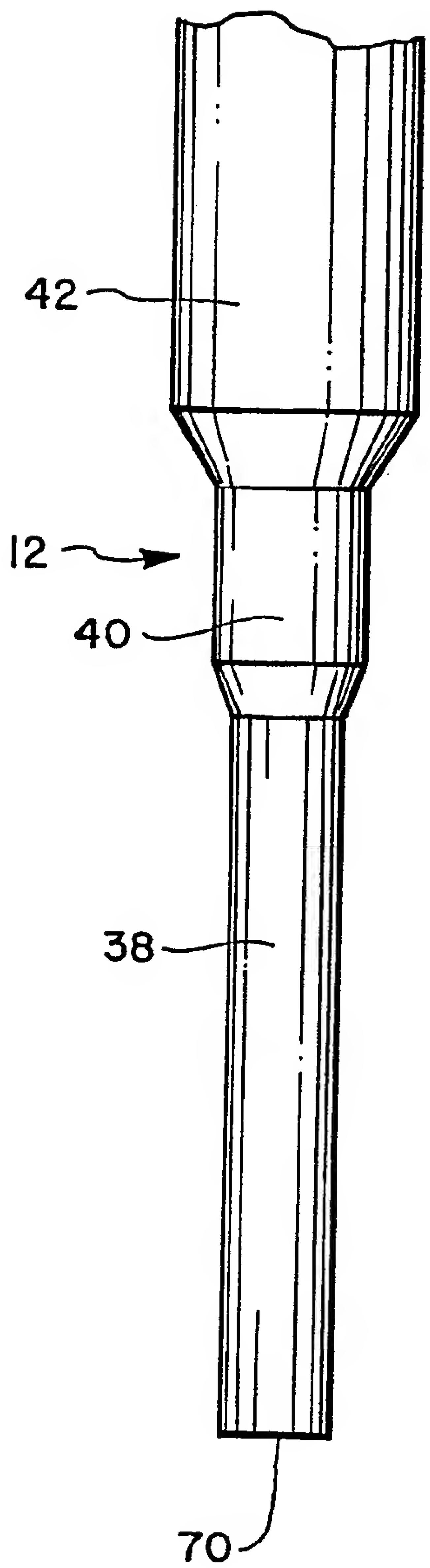


FIG. 12B

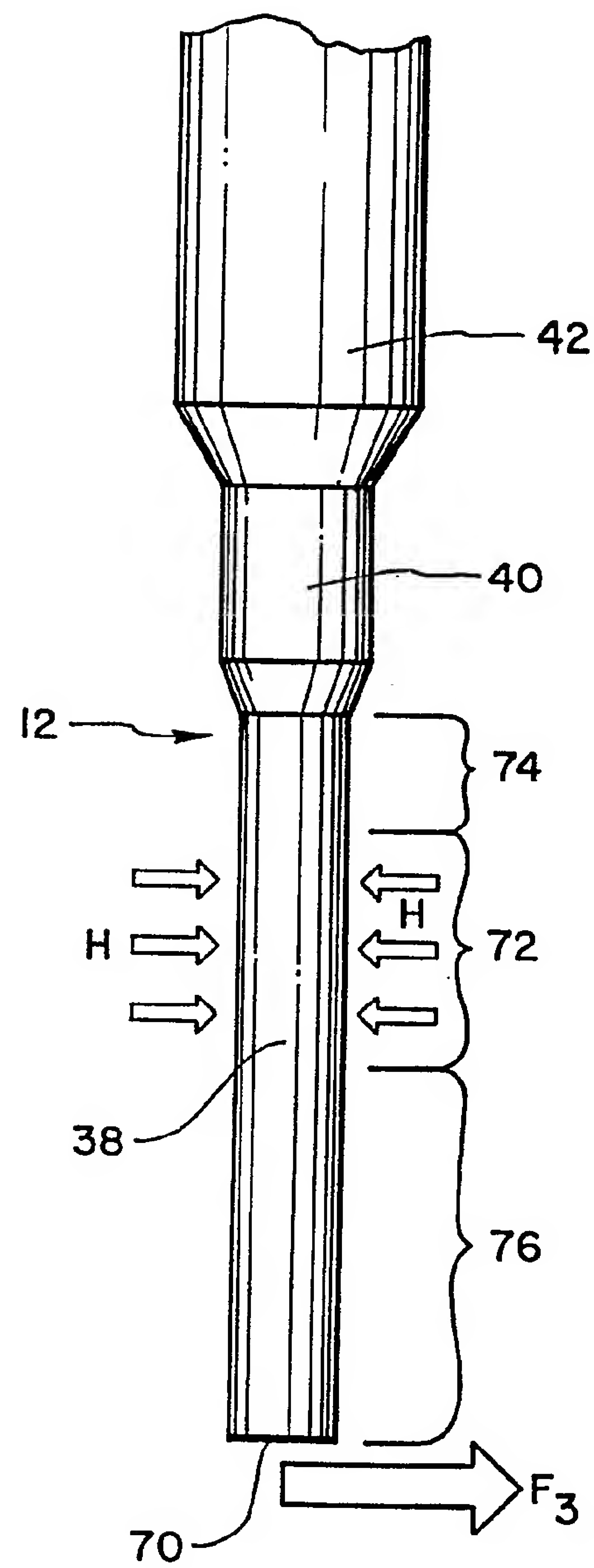


FIG. 12C

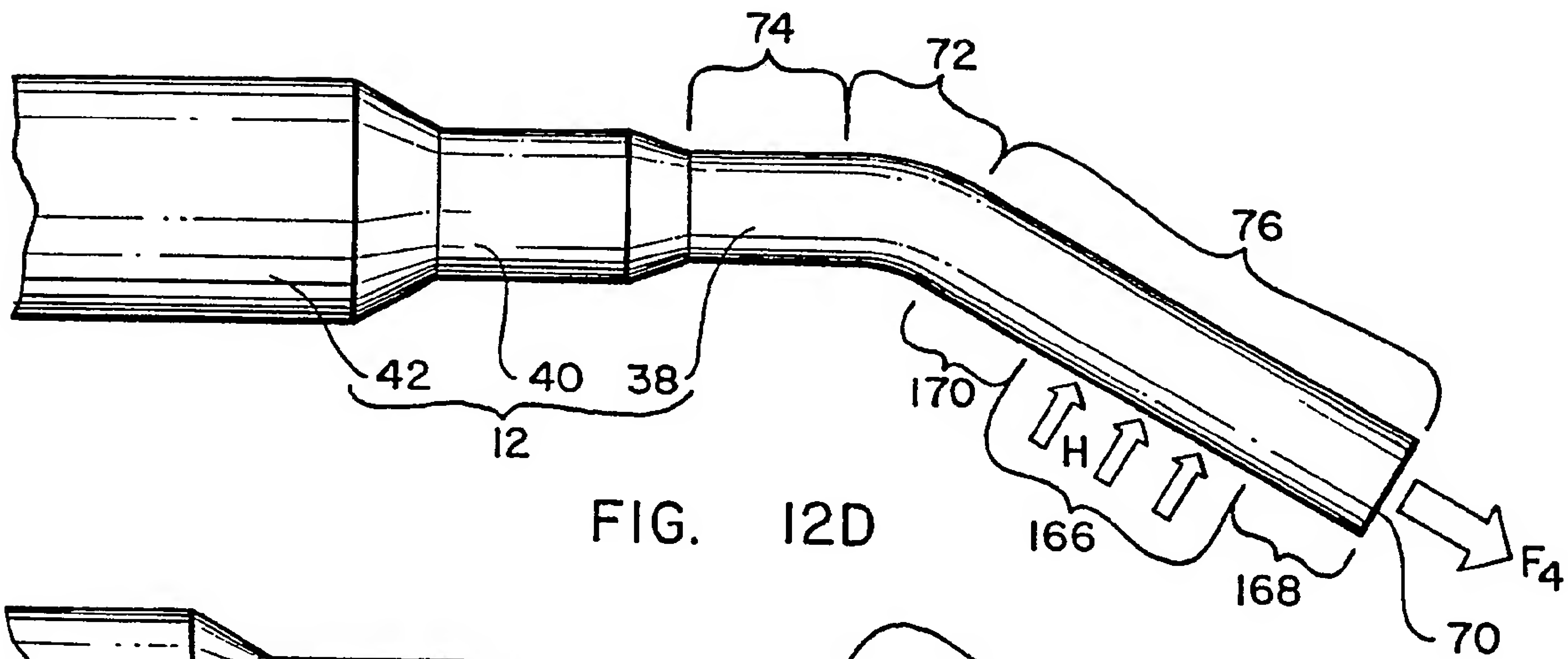


FIG. 12D

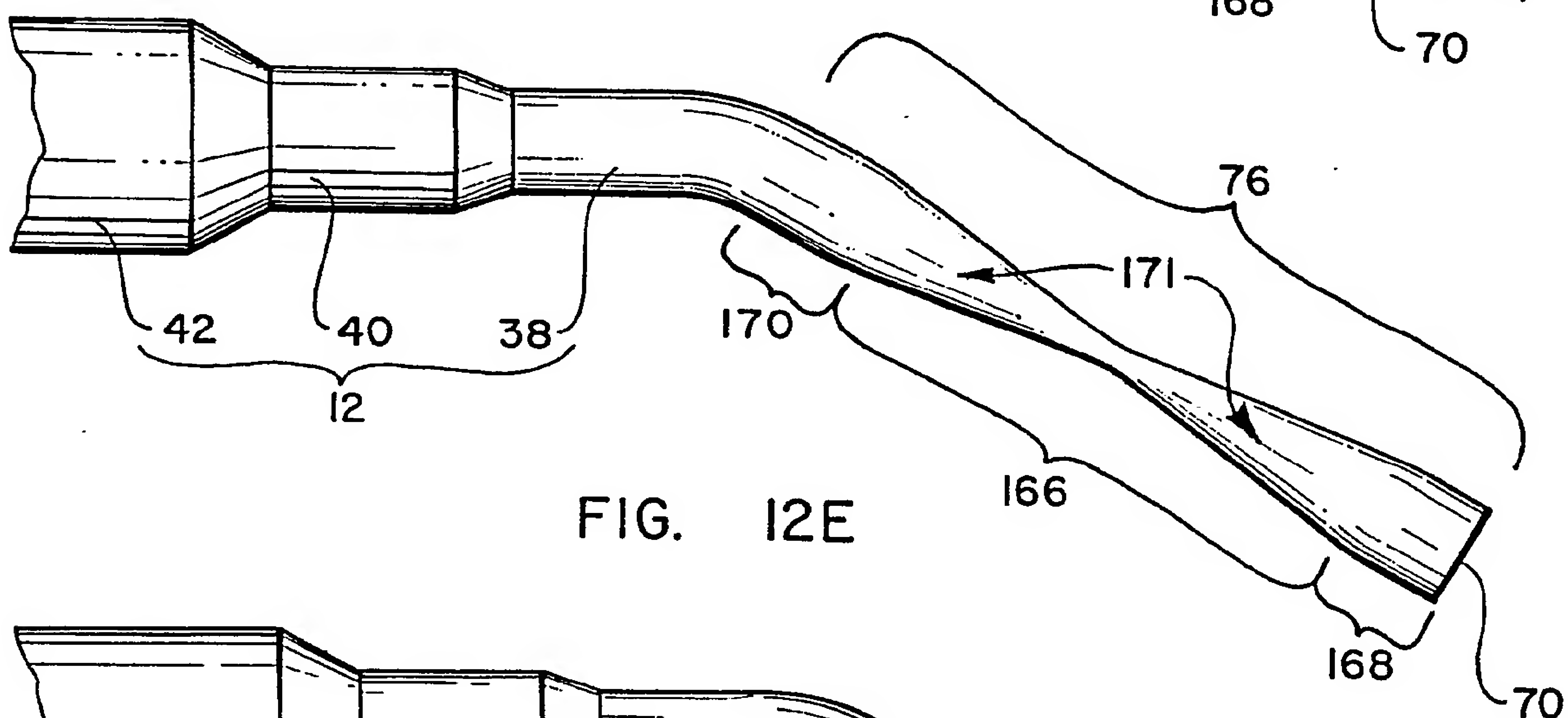


FIG. 12E

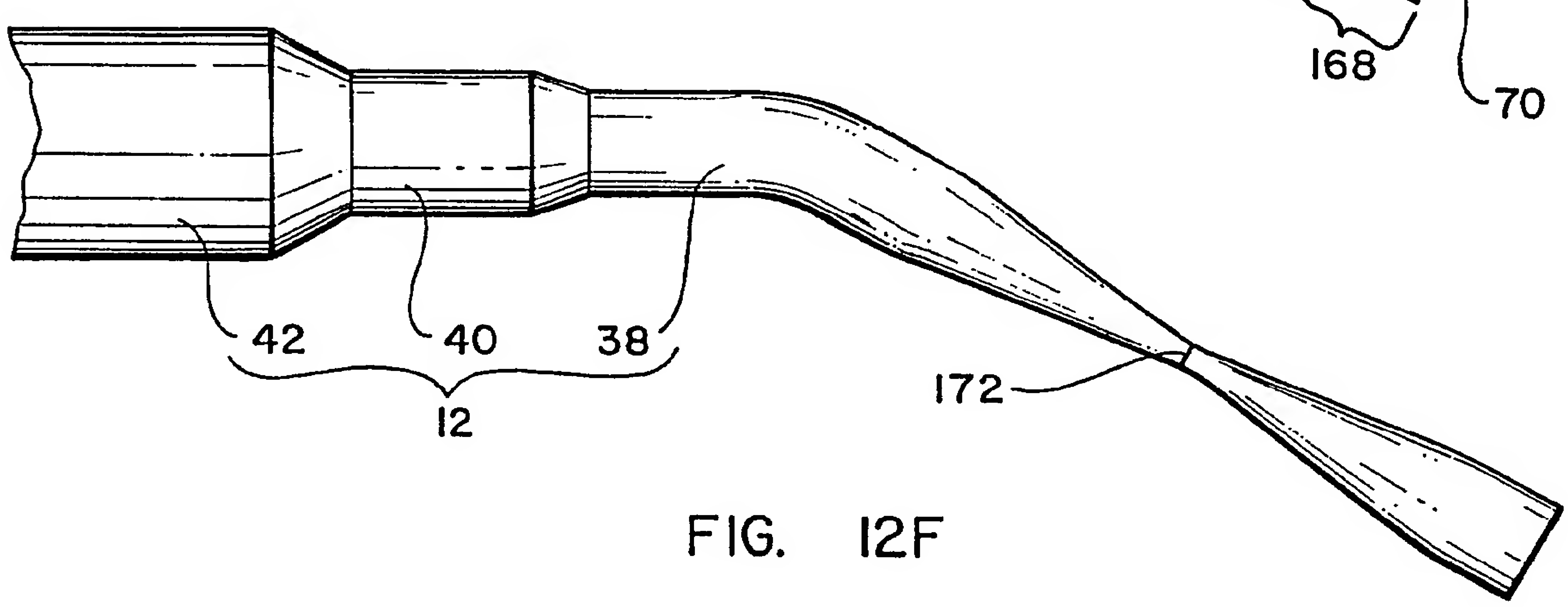


FIG. 12F

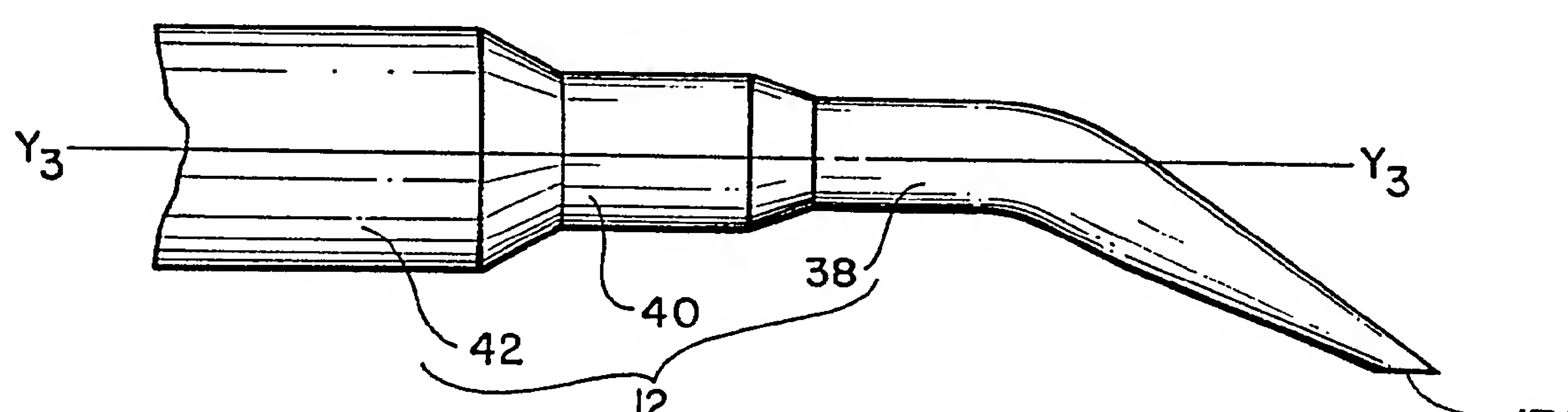


FIG. 12G

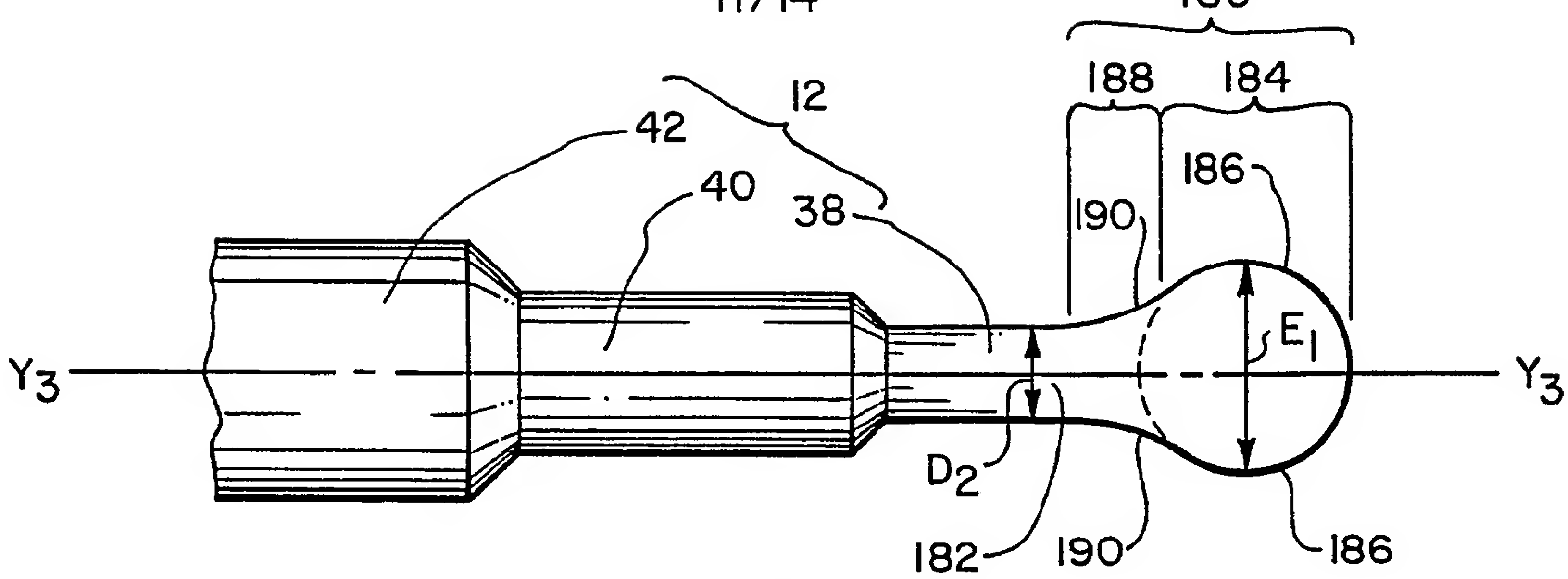

180
188
184
12
42
186
40
38
190
Y_3
E_1
Y_3
D_2
182
190
186

FIG. 13

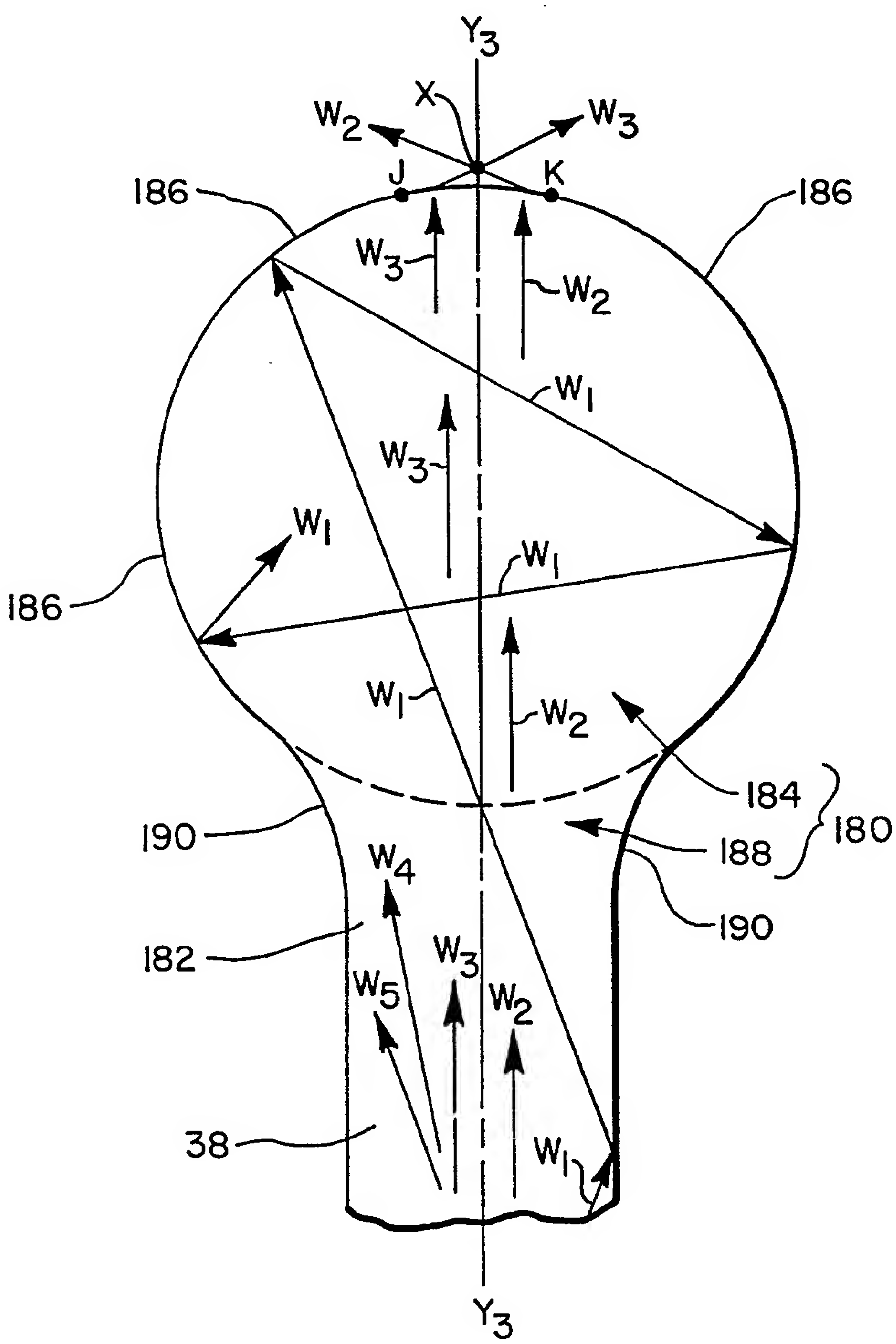
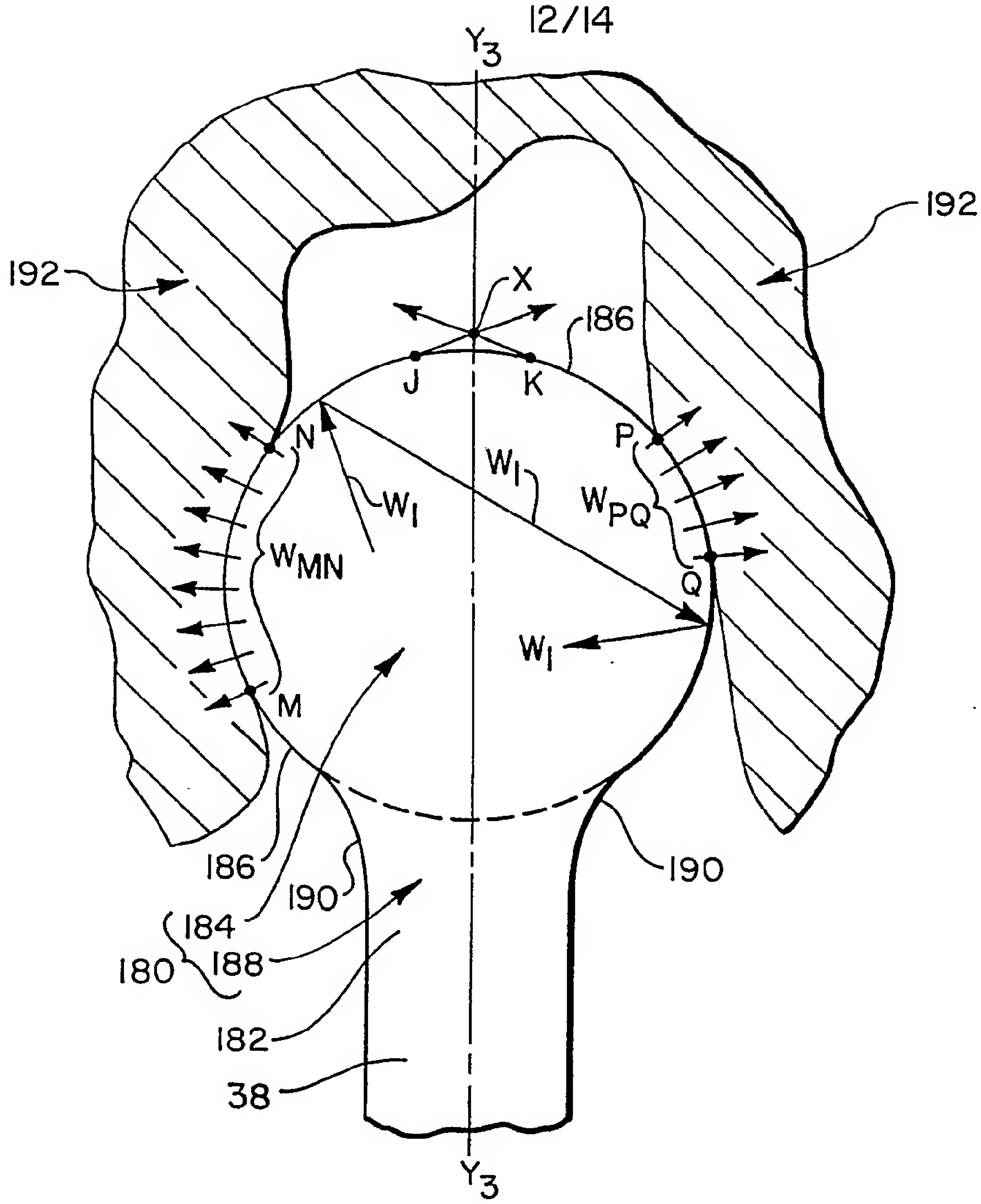
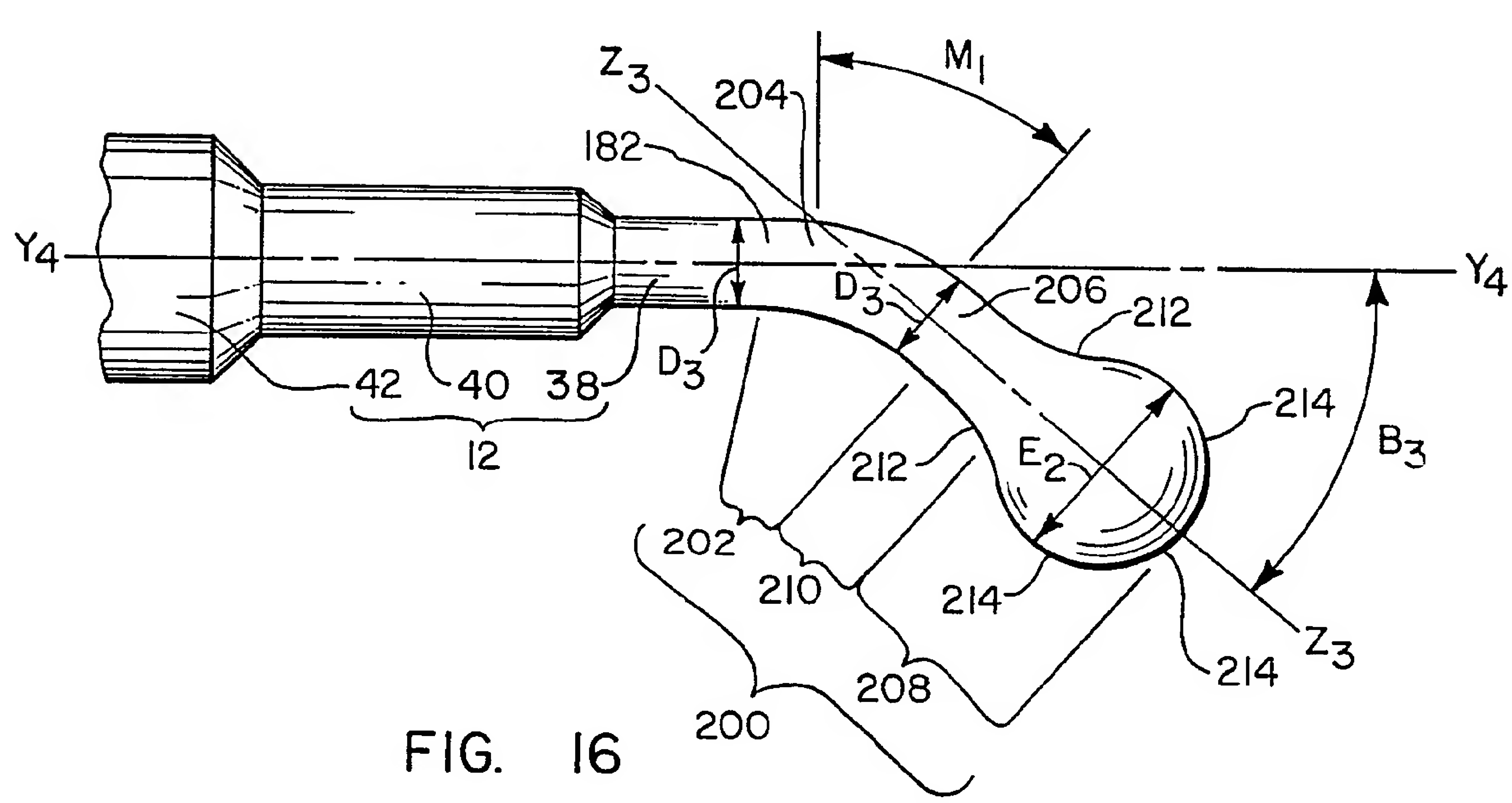

Y_3
X
W_2
W_3
J
K
186
186
W_3
W_2
W_1
W_3
W_1
W_1
186
W_1
W_2
184
180
190
188
W_4
190
182
W_3
W_5
W_2
38
W_1
Y_3

FIG. 14



Y3
192
192
X
186
J
K
N
P
W1
W1
W1
WPQ
WMN
Q
W1
M
186
190
190
184
180
188
182
38
Y3

FIG. 15



Z3
204
M1
182
Y4
Y4
D3
206
212
D3
42
40
38
214
12
212
E2
B3
202
210
214
Z3
214
208
200

FIG. 16

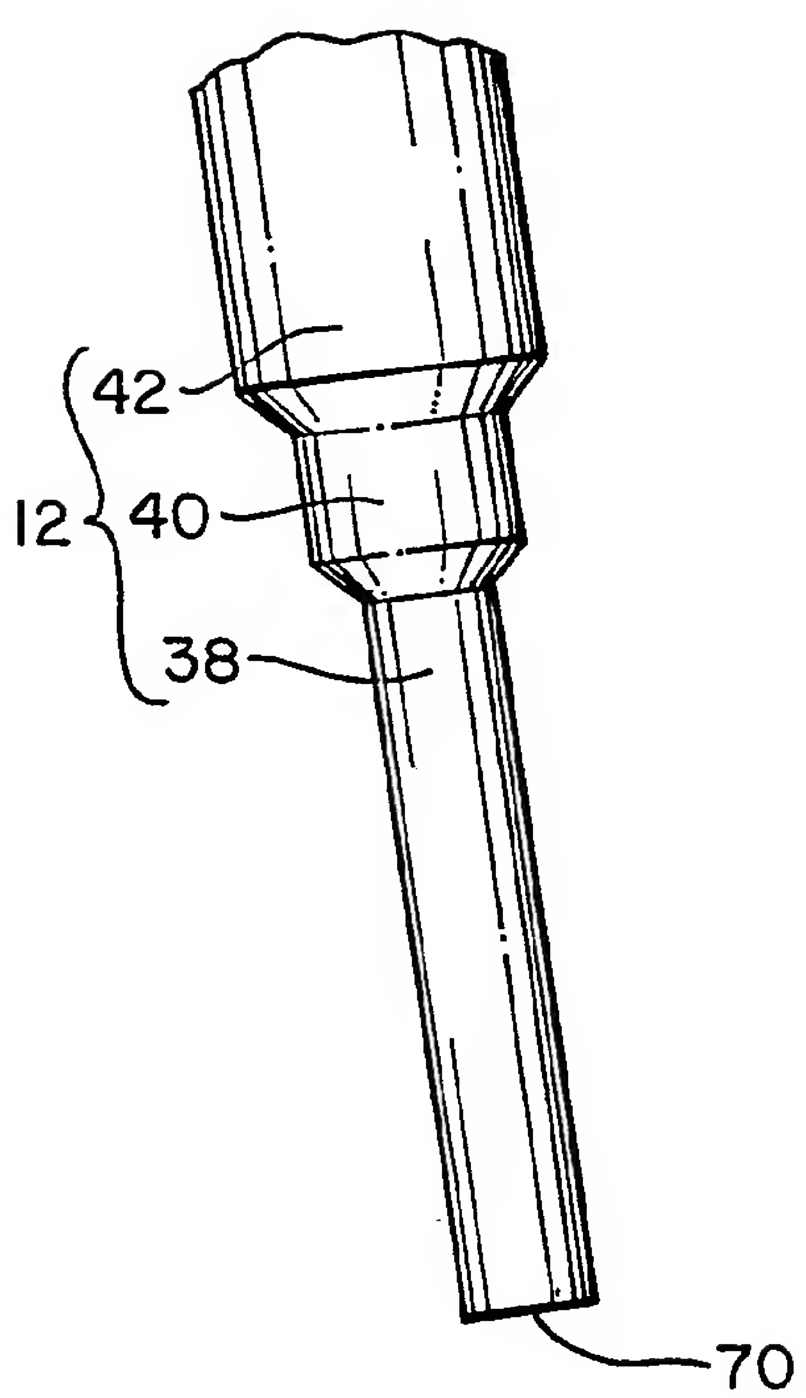


FIG. 17A

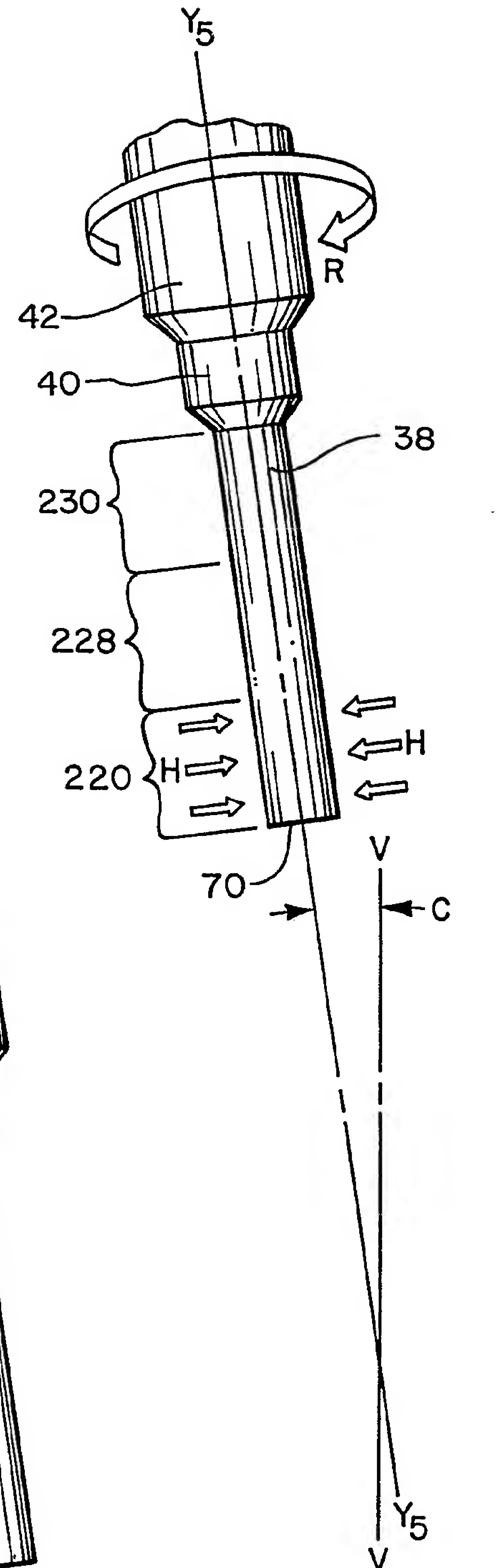


FIG. 17B

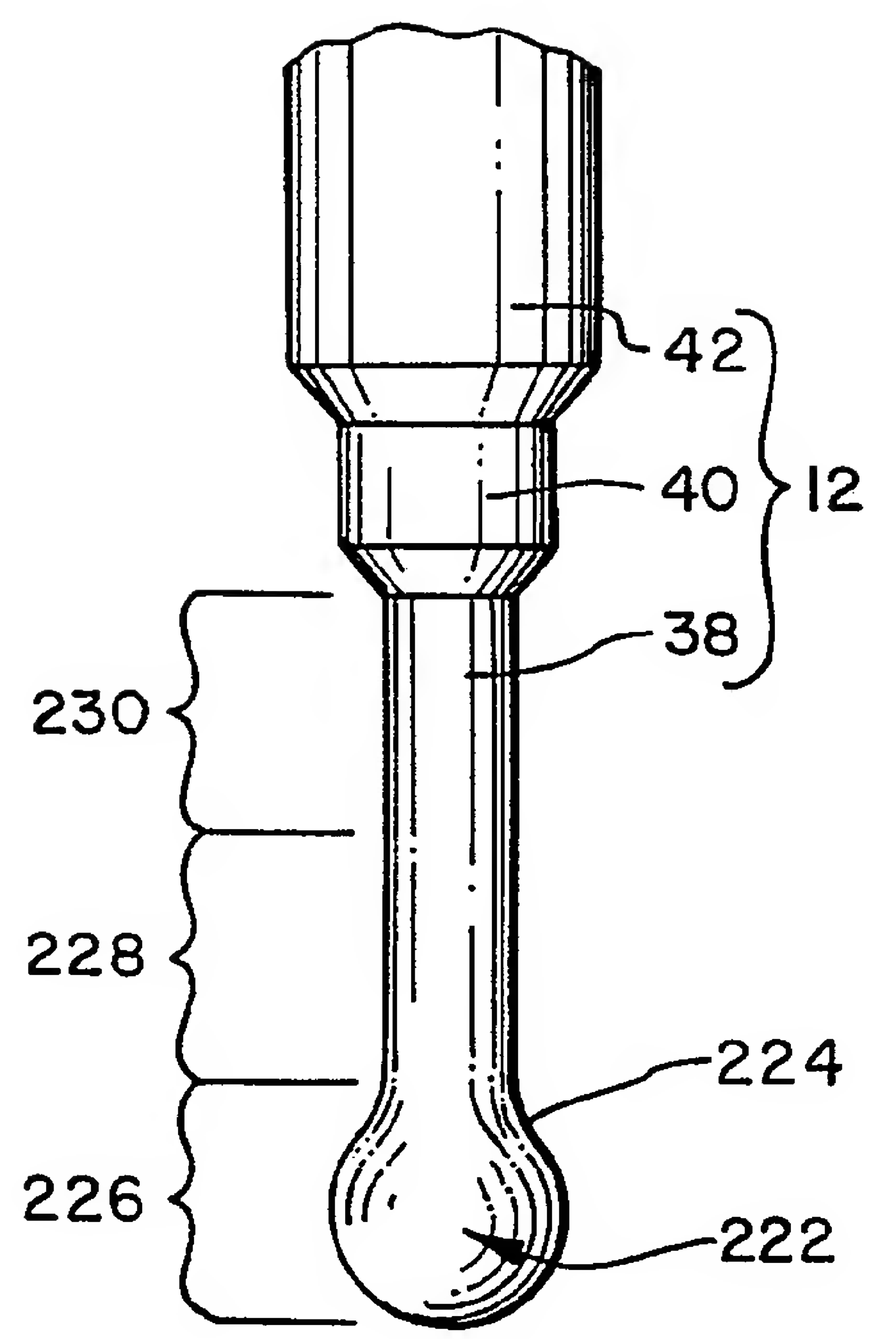


FIG. 17C

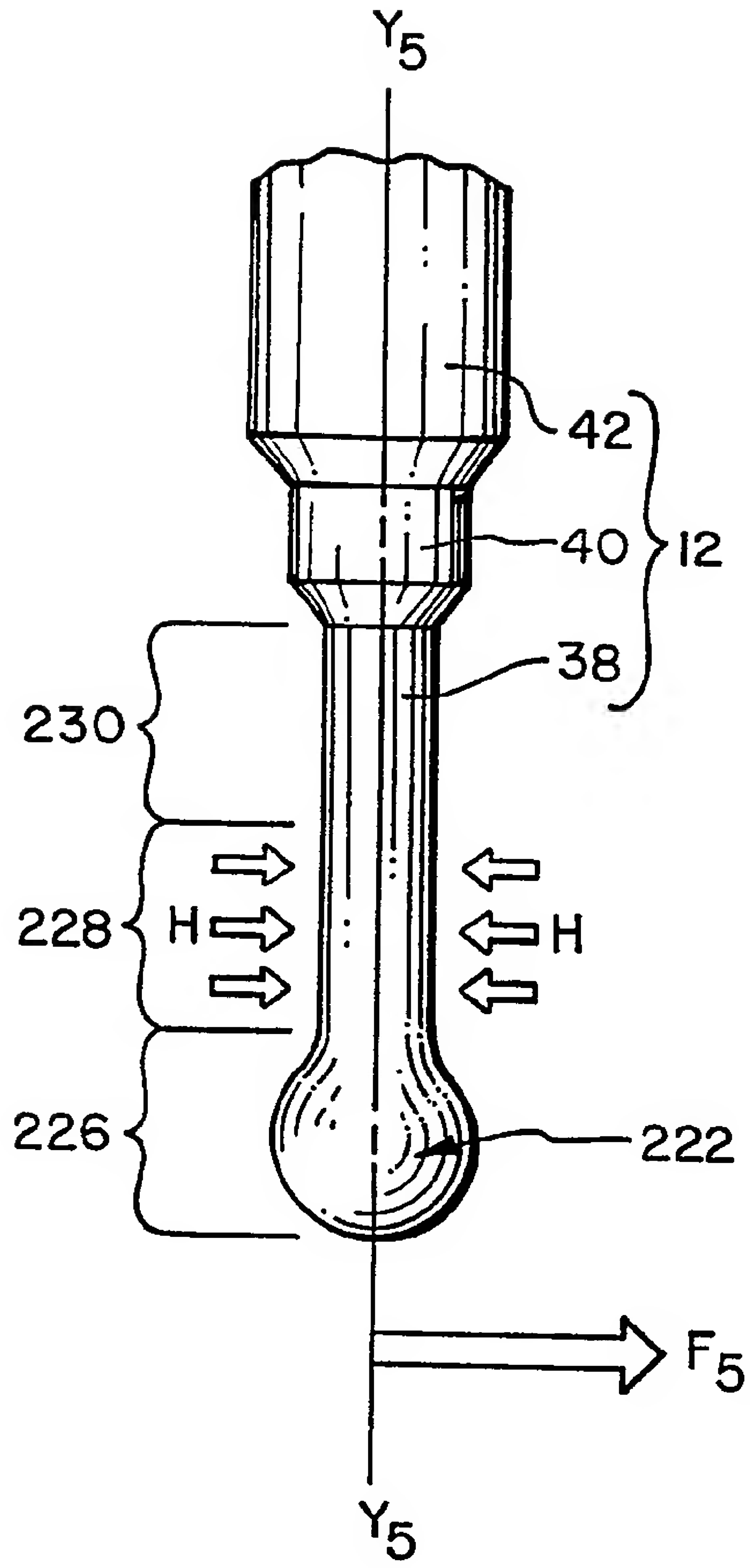


FIG. 17D

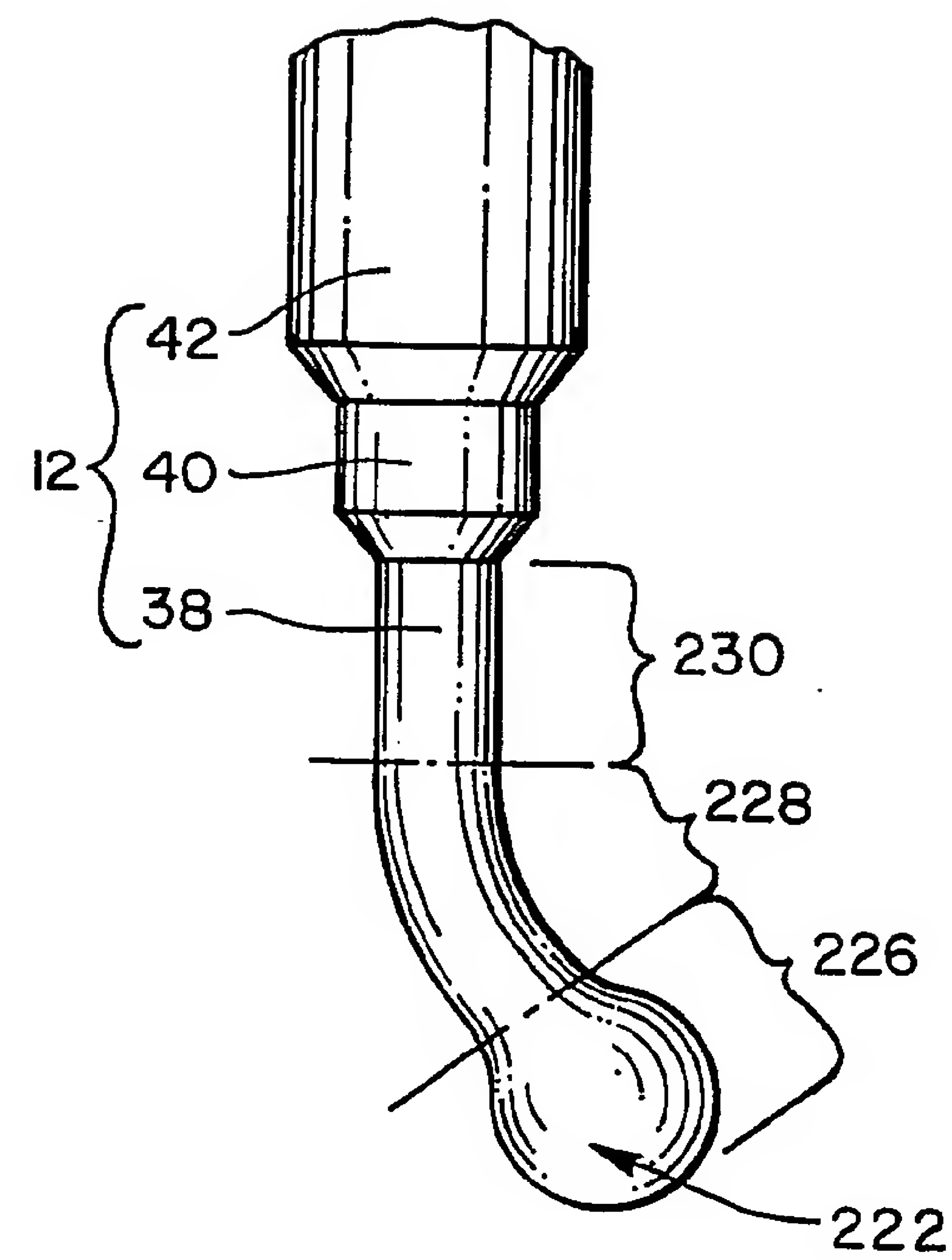


FIG. 17E

INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/04658

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) : A61N 5/06
U.S. Cl : 128/395,397,398; 606/7,13-17

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/395,347,348; 65/2,10.2,23,37,40,102; 606/7,13-17

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	EP,A 142,026 (RUSSO) 22 May 1985 See the entire document.	1-9,11-21,32-34,39-47,50-56,60-62,64,67-70,73 10,22-31,35-38,48,49,57-59,63,65,66,71,72,74-77
X Y	US,A 3,288,585 (CLARKE) 29 November 1966 See the entire document.	74,75 76,77
Y	US,A 4,826,431 (FUJIMURA) 02 May 1989 See the entire document.	10,22-31,34,35,65
Y	US,A 4,849,859 (NAGASAWA) 18 July 1989 See the entire document.	34-38

(CON'T)

* Special categories of cited documents: [15]
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
13 NOVMEBER 1990	11 JAN 1991
International Searching Authority [1]	**Signature of Authorized Officer** [20]
ISA/US	for Andrew Robinson DAVID SHAY